UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EISAI CO., LTD. and EISAI INC.,

Plaintiffs,

-v.-

DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC.,

Defendants.

03 Civ. 9053 (GEL)

OPINION AND ORDER

EISAI CO., LTD. and EISAI INC.,

Plaintiffs,

-v.-

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

03 Civ. 9223 (GEL)

Robert L. Baechtold, Joseph M. O'Malley, Bruce M. Wexler, Fitzpatrick, Cella, Harper & Scinto, New York, NY; David B. Tulchin, James T. Williams, and Bradley A. Harsch, Sullivan & Cromwell LLP, New York, NY, for Plaintiffs.

Maurice B. Ross, Louis H. Weinstein, Ellen T. Lowenthal, Nathaniel I. Watts, Budd Larner, P.C., Short Hills, NJ, for Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories Inc.

David M. Hashmall, Frederick H. Rein, and Elaine Herrmann Blais, Goodwin Proctor LLP, New York, NY, for Defendant Teva Pharmaceuticals USA, Inc.

GERARD E. LYNCH, District Judge:

The Hatch-Waxman Act, 21 U.S.C. § 355 and 35 U.S.C. § 271(e) (1994) (codified as amended), permits would-be manufacturers of generic versions of an already approved, patented drug to seek expedited approval from the Food and Drug Administration ("FDA") before expiration of the patent, by means of an Abbreviated New Drug Application ("ANDA"). See Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1342 (Fed. Cir. 2000). Filing an ANDA constitutes an "artificial" but legally cognizable instance of patent infringement, often triggering a lawsuit in which the validity and enforceability of the patent may be tested. Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1344 (2004).

Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc. (collectively, "Reddy"), and Teva Pharmaceuticals USA, Inc. ("Teva"), the defendants in these actions, each filed an ANDA, seeking to manufacture generic versions of a gastric-acid inhibitor that is marketed under the brand name Aciphex. Plaintiffs Eisai Co., Ltd. and Eisai Inc. (collectively, "Eisai"), hold the patent on rabeprazole sodium, the active ingredient of Aciphex. Eisai duly brought these actions for patent infringement against defendants.[1] Defendants argue that Eisai's patent should not be enforced because Eisai engaged in inequitable conduct before the U.S. Patent and Trademark Office ("PTO") during prosecution of its patent application. Eisai now moves for summary judgment on all defendants' allegations of inequitable conduct. For the

[1] A third action, brought by Eisai against Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan"), has been stayed pending the outcome of these actions. Mylan has stipulated to be bound by the final judgments and any decisions on appeal in these related actions. See Stipulation and Order, Eisai Co., Ltd. v. Mylan Laboratories, Inc., No. 04 Civ. 656 (GEL) (S.D.N.Y. Nov. 3, 2004).

reasons below, the motion is granted in part, but for the most part denied.[2]

THE PATENT PROSECUTIONS

To address the parties' contentions requires reciting in some detail the history of the prosecutions of both the rabeprazole patent and another Eisai patent application that defendants argue is closely related. The following facts regarding those prosecutions are undisputed except as otherwise noted. Given the scope and somewhat specialized nature of the record, however, citations are provided to identify the source of certain facts. Where citations point to a statement in a party's brief or other non-evidentiary submission, that statement is generally uncontested and usually itself points to evidentiary material in the record.

I. Prosecution of The Patent-in-Suit

Eisai, a pharmaceutical company, owns U.S. Patent No. 5,045,552 ("'552 patent"), the patent-in-suit. The '552 patent claims, among other things, the chemical compound rabeprazole and its salts.[3] Rabeprazole sodium is the active ingredient in a drug that Eisai developed and made commercially available under the brand name Aciphex. The drug was approved by the FDA in 1991 for treatment of certain gastric ailments including duodenal ulcers and heartburn. Rabeprazole functions as a "proton pump inhibitor," because it suppresses gastric-acid production by inhibiting the action of an enzyme, H^+K^+ATPase, which pumps into the stomach

[2] Reddy does not challenge the validity of the patent. Teva does, on the ground of obviousness in light of a combination of prior art. Teva's claim of invalidity is addressed in a separate, companion opinion issued this day, Eisai Co., Ltd. v. Teva Pharmaceuticals USA, Inc., ___ F. Supp.2d ___ (S.D.N.Y. Oct. 5, 2006).

[3] For the sake of simplicity, rabeprazole and its salts are usually referred to in this Opinion simply as "rabeprazole." No issue raised by this motion requires distinguishing the various forms of rabeprazole.

protons (H^+ ions) that combine with chloride ions to form hydrochloric (gastric) acid. (Ds. Joint R. 56.1 Stmt. ¶ 15.) The market for Aciphex is a lucrative one: Eisai's worldwide sales of the drug have been reported at over $1 billion per year. (Ds. Joint R. 56.1 Stmt. ¶¶ 1-5.)

On November 10, 1987, Eisai's attorney Arthur R. Crawford filed the application that resulted in the '552 patent.[4] ('552 File History, DRLRAB 51.)[5] The application reported that the compound now referred to as rabeprazole[6] belonged to a known class whose chemical structures include a benzimidazole ring on the left side of the molecule as diagramed in the standard chemical notation, and a pyridine ring on the right, joined by a sulfinylmethyl group. (P. Ex. 1, '552 patent, col. 1, lines 40-44.) Numerous compounds feature this basic chemical structure, including prominently omeprazole, the first commercially available proton pump inhibitor; omeprazole was disclosed in a group of patents (known as "Junggren" after an

---

[4] Crawford served as the primary prosecuting attorney for Eisai in all actions relevant to the inequitable conduct issue. He was retained by Mitsuo Taniguchi, then the Eisai employee in charge of patenting pharmaceutical compounds, who had helped draft the applications in issue. Taniguchi remained involved in the applications' prosecution, sometimes communicating with Crawford about PTO issues directly and at other times through Japanese law firm Furuya & Co. (Teva Ex. 63, Taniguchi Tr. 20:2-25, 32:25-33:21, 38:13-17, 45:2-10, 62:5-23, 75:9-76:13, 86:18-88:14; Teva Ex. 60, Crawford Tr. 53:14-54:20.)

[5] The parties' submissions refer to the key patent applications in inconsistent fashion. The application that eventually issued as patent '552 was originally filed as U.S. Patent Application No. 07/119,386. The parties sometimes, but not usually, refer to it as the "'386 application." (See, e.g., Ds. Joint R. 56.1 Stmt. ¶ 33.) Similarly, the application that issued as patent '013, discussed infra, was filed as Application No. 07/207,626 and is sometimes referred to in the submissions by the "'626" designation. (See, e.g., Reddy Ex. 39, Smith Rep. 5.) For the sake of readability – and because the parties have submitted the patents' file histories according to their final numbers – the Court will refer to the two applications by their final patent numbers only, as the '552 patent application and the '013 patent application respectively.

[6] Rabeprazole was claim 7 of the original application, and the application's specification disclosed the structure of rabeprazole sodium as Compound 19 and Example 33. (See '552 Patent File History, DRLRAB 70,74.)

inventor) owned by the Swedish company now known as AstraZeneca AB. It is the active ingredient in the drug marketed as Prilosec.[7] (Ds. Joint R. 56.1 Stmt ¶ 19; '552 Patent File History, DRLRAB 54, 431; see also Teva Mem. in Opp. to P. Mot. for Summ. J. of Patent Validity, 1-2.) The compounds are formally distinguishable primarily by the particular "substitutions" of chemical groups for hydrogen atoms around their pyridine rings. The structure of rabeprazole's pyridine ring reflects a pattern of substitution referred to in this litigation as "asymmetrical," because its 3-position is substituted (with a methyl group) while the 5-position is unsubstituted (that is, it is bonded to a hydrogen atom); the 4-position is substituted with a methoxypropoxy group ($OCH_2CH_2CH_2OCH_3$), a type of alkoxy group.[8] (P. Mem., glossary at 7.) Other related compounds, some of which are potentially useful in the inhibition of gastric-acid formation, have different patterns of pyridine-ring substitution, including the use of different alkoxy groups at the 4-position. The benzimidazole ring of rabeprazole is unsubstituted. (Id.)

Eisai reported having synthesized rabeprazole by working from omeprazole. (P. R. 56.1 Stmt. ¶¶ 18, 24.) Eisai disclosed summaries of three sets of pharmacological data comparing,

---

[7] Another related compound, lansoprazole, which is discussed in relation to certain issues below, is the active ingredient in yet another prominent brand-name acid inhibitor, Prevacid. (See Teva Mem. in Opp. to P. Mot. for Summ. J. of Patent Validity, 1-2.)

[8] Certain record items, seemingly restricted to the '552 and '013 patents' file histories, refer to what is clearly the 5-position (two to the right of the 3-position) in diagrams of the pyridine ring as "R^4." (See, e.g., '552 Patent File History, DRLRAB 231.) The confusion of labels was raised, for instance, in defendants' deposition of Eisai's Taniguchi. (See Teva Ex. 63, Taniguchi Tr. 89:14-91:12.) No party has suggested that the defendants' 5-position and the plaintiffs' "R^4" refer to different locations; indeed, the substantive arguments of both sides assume that the two labels point to precisely the same place. For the sake of simplicity, the Court refers to this position as the 5-position.

relevantly, omeprazole to rabeprazole. (Ds. Joint R. 56.1 Stmt. ¶ 37.) These disclosures will be further discussed in relation to defendants' inequitable conduct claims, but, in brief, they purported to demonstrate rabeprazole's superior potency and its enabling of faster post-dosage recovery of acid secretion as compared to omeprazole.[9] (P. R. 56.1 Stmt. ¶¶ 19, 21, 23-27, 36-39 (citing '552 patent)). The submitted data were not the only existing pharmacological comparisons involving rabeprazole, as will further be discussed in relation to the inequitable conduct claims.

A. First Rejection and Eisai's Response

Patent examiner Jane Fan rejected the rabeprazole claims three times, prompting various persuasive efforts by Eisai, before ultimately allowing the claims to issue as the '552 patent. On September 21, 1988, Fan rejected the claims as obvious in light of certain prior art: the Junggren patents and Great Britain Patent No. 2,234,523 ("GB '523"). (Ds. Joint R. 56.1 Stmt. ¶¶ 41-42.) "[Junggren] and [GB '523] generically teach[] R^4 [the 4-position on the pyridine ring] being methoxyethoxy or ethoxyethoxy," wrote Fan.[10] ('552 File History at DRLRAB 292.) Fan specifically cited and diagramed a prior art-compound, Example 27 of Junggren, which bears a methoxyethoxy substituent at the 4-position of its pyridine ring. ('552 File History, DRLRAB 292-93.) Fan concluded that the "[prior] art compounds are homologs of the claimed compounds rendering the claimed compounds unpatentable." (Id. at 293.) The rejection of the rabeprazole

[9] Defendants dispute the reliability or presentation of all these test results. (See Ds. Joint R. 56.1 Stmt. ¶¶ 37-39.) Their existence and disclosure to the PTO are not, however, in dispute.

[10] Methoxyethoxy ($OCH_2CH_2OCH_3$) and ethoxyethoxy ($OCH_2CH_2OCH_2OCH_3$) are – like rabeprazole's 4-position pyridine-ring substituent, methoxypropoxy – types of alkoxy groups. (P. Mem., glossary at 2.)

claims was not based on lack of novelty. (Ds. Joint R. 56.1 Stmt. ¶ 42.)

Eisai reacted to this first rejection in various ways. On March 21, 1989, Eisai attorney Crawford offered a response that addressed both the structural and functional distinctiveness of rabeprazole. With respect to chemical structure, the response distinguished rabeprazole's 4-position substituent, methoxypropoxy, from those of compounds in the prior art. Eisai submitted that Junggren and GB '523 disclosed only compounds bearing a methoxy*ethoxy* group at the 4-position of the pyridine ring and "thus novelty is established" – presumably, although not explicitly, contrasting rabeprazole's methoxy*propoxy* substituent. ('552 Patent File History, DRLRAB 429.) Further, Eisai pointed out that the "[s]pecific compounds disclosed in [GB '523] and [Junggren] are substituted at both the 3- and 5-position by methyl groups, as in the GB ['523] patent, or unsubstituted in both the 3- and 5-positions." (Id. at DRLRAB 429, emphasis in original.) The response continued, "Applicants' claims allow for the possibility of unsubstitution or a lower alkyl at the 3-position with no substitution at the 5-position; preferably, the 3-position . . . is methyl" – describing the asymmetrical pyridine-ring substitution pattern that is found in rabeprazole. (Id.)

In addition to discussing structural traits, Eisai's March 21 response also addressed the pharmacological properties of the claimed compounds. Eisai professed that compounds "in which the substituent at the 4-position is propoxymethoxy"[11] exhibited "unexpected anti-ulcer activity." ('552 Patent File History, DRLRAB 429.) It also submitted additional pharmacological comparisons with omeprazole, alleging omeprazole's overall inferiority with

[11] No party has raised an issue on this motion that requires distinguishing "methoxypropoxy" from "propoxymethoxy."

respect to acid-inhibition and post-dosage recovery. (Id. at DRLRAB 541.)[12] The response sought to justify Eisai's choice of omeprazole as a comparator:

> As . . . the [prior] art shows a preference for a specific compound currently under development and known as Omeprazole, . . . applicants have compared their elected compound with Omeoprazole [*sic*] and not compounds more nearly structurally related to the claimed compounds . . . . This is appropriate in accordance with In re Fouche, [439 F.2d 1237 (C.C.P.A. 1971),] where the Court accepted a showing of unexpected advantage over a structurally more remote compound because the prior art clearly showed a preference for this structurally more remote compound.

('552 Patent File History, DRLRAB 430.)

In a May 4, 1989, "Supplemental Response," Eisai offered still further omeprazole-related arguments in favor of its claimed compounds' superiority, again explaining its choice of omeprazole as comparator: "The prior publications and patents describe a host of substituted benzimidazole compounds having antisecretory activity . . . . Among these compounds, the single most interesting compound is known as omeprazol[e]." ('552 Patent File History, DRLRAB 437-38.) The response presented certain test comparisons as showing the superior acid-inhibition properties of Eisai's claimed compounds. (Id. at 438-39.)

Also in response to the first rejection, Eisai submitted a copy of a prior-art application to European Patent No. 167,943 (referred to as "Beecham") which it had mentioned in the '552 patent application. ('552 Patent File History, DRLRAB 354-418.) The Beecham application discloses the asymmetric pyridine-ring substitution pattern of rabeprazole (substitutions at the 3- and 4- positions, with none at the 5-position), but does not disclose a methoxypropoxy or

[12] This page appears out of order in the file history, immediately following DRLRAB 435.

methoxyethoxy group at the 4-position. (See id.)

B. Second Rejection and Eisai's Response

On July 14, 1989, unsatisfied by Eisai's further submissions, Fan issued her second rejection of the rabeprazole claims based on the same prior art references. Referring to Eisai's March 21 submission asserting the distinctiveness of rabeprazole's asymmetrical substitution pattern, she expressed incomprehension, writing, "The claimed compounds encompass both 3.5 positions [3- and 5-positions] substituted by lower alkyl, thus the statement at middle part of page 9 of applicants' remark is not understood." ('552 Patent File History, DRLRAB 441.) Additionally, Fan rejected Eisai's reasoning in submitting comparison data for omeprazole rather than for a structurally closer prior-art compound: "The rationale of In re Fouche does not apply herein since isomeric difference [from the prior art] is noted therein whereas in the instant case homologous difference exists. Furthermore, a single compound is claimed in [F]ouche whereas a great many compounds are claimed in the instant case." (Id.) She continued, "In the unpredictable medicinal field, one can not assume a compound's pharmaceutical activity. Actual comparison has to be made in order to establish unexpected property."[13] (Id.)

---

[13] The parties dispute the intended meaning of these comments by the patent examiner. Defendants read Fan's "not understood" statement as merely reflecting the fact that the '552 application at the time still encompassed, along with *asymmetrically* substituted compounds such as rabeprazole, compounds with *symmetrically* substituted pyridine rings. In such a context, any patentability argument based on asymmetrical substitution would, indeed, have been difficult to understand. (Ds. Joint R. 56.1 Stmt. ¶ 54.) Eisai, on the other hand, interprets the "not understood" comment as Fan's altogether dismissing the asymmetry-as-novelty argument for superfluousness, as her first rejection had not charged lack of novelty. (Killworth Decl. ¶¶110-23.) In other words, as Eisai would have it, Fan did not understand why the applicant was arguing novelty when she had never raised the issue. The significance of these differing interpretations with respect to defendants' claims of inequitable conduct will be discussed below.

Also disputed is Fan's intention in rejecting Eisai's rationale for submitting data comparing omeprazole rather than a structurally closer compound. Eisai presents her comments

Crawford spoke with Fan on August 3, 1989, after she rejected the rabeprazole claims for the second time. (P. R. 56.1 Stmt. ¶ 56.) Fan's record of the discussion states, in pertinent part, "If applicants are willing to limit the invention to [rabeprazole], then only methoxyethoxy cpd need [*sic*] to be compared."[14] ('552 File History, DRLRAB 449.) On December 28, 1989, Crawford filed a continuation of the rabeprazole application, to avoid expiration of the claims.

C. Third Rejection and Eisai's Response

On July 17, 1990, Fan issued her third rejection of the rabeprazole application. She reiterated reasons from prior rejections, including that the claimed compounds were obvious in light of prior art, that Eisai's argument concerning asymmetric substitution was "not understood," that Eisai's rationale for comparing only omeprazole was not persuasive, and that "[a]ctual comparison has to be made in order to establish unexpected property." ('552 Patent File History, DRLRAB 455-56.) This time, however, she added, "The closest prior art compounds should be compared with the claimed compounds." ('552 File History, DRLRAB 455.) "In the instant case," she continued, certain prior-art compounds "should all be compared," identifying in particular Example 27 of Junggren and "the compounds of EP 74341," a "newly cited" prior art application that Fan referred to in her third rejection as "Carlsson." (Id.

---

as a flat "refus[al]" to consider any omeprazole-comparisons at all. (P. R. 56.1 Stmt. ¶ 55.) Defendants, on the other hand, again note that Fan was at that point examining an application claiming numerous compounds, not just rabeprazole, and thus read her comments not as refusing all comparisons of omeprazole with rabeprazole, but rather as deeming omeprazole-comparisons inadequate to sustain the application as it stood. (Ds. Joint R. 56.1 Stmt. ¶ 55.) Again, the significance of the different readings with respect to defendants' claims will be discussed below.

[14] The parties also dispute the intended meaning of this writing. The grammatical ambiguity leaves unclear whether Fan sought comparison to a single methoxyethoxy compound in particular or comparisons to methoxyethoxy compounds generally – a question that bears on Eisai's performance in response, as discussed later in regard to defendants' claims.

at 455, 457.)

Following Fan's third rejection of the '552 patent application, Eisai both narrowed its claims and attempted to strengthen its substantive case. On January 11, 1991, Eisai submitted an amendment, limiting its claims to only those relating to rabeprazole. ('552 Patent File History, DRLRAB 464-66.) On the same date Eisai submitted a Rule 132 declaration[15] – known in this litigation as the "Fujisaki Declaration," as its contents are attested by Eisai inventor Hideaki Fujisaki – purporting to show rabeprazole's superior performance in an in vitro acid-inhibition test comparing three compounds, Example 27 of Junggren and two others. ('552 Patent File History, DRLRAB 468-471.) "I compared the . . . four compounds for their ability to inhibit H^+K^+ATPase, an assessment of the compound's ability to inhibit the secretion of gastric acid," Fujisaki reported. (Id. at 469.)

None of the three comparators (compounds 2, 3, and 4) shares rabeprazole's (compound 1) asymmetrical pyridine-ring substitution pattern, instead exhibiting substitution or no

---

[15] A "Rule 132 declaration" refers to the submission applicants are permitted by regulation to offer in response to certain rejections. The regulation effective at the pertinent time provided:

> When any claim of an application or a patent under reexamination is rejected on reference to a domestic patent which substantially shows or describes but does not claim the invention, or on reference to a foreign patent, or to a printed publication, or to facts within the personal knowledge of an employee of the Office, or when rejected upon a mode or capability of operation attributed to a reference, or because the alleged invention is held to be inoperative or lacking in utility, or frivolous or injurious to public health or morals, affidavits or declarations traversing these references or objections may be received.

37 C.F.R. § 1.132 (1991). Claimed compounds rejected for structural obviousness might nevertheless prevail upon the filing of a Rule 132 declaration that persuasively showed "unexpected properties." (See Killworth Decl. ¶ 28; see also Stoner Decl. ¶ 85.)

substitution at both their 3- and 5-positions. (Id. at DRLRAB 470.) But in an accompanying submission by Crawford, Eisai did not mention the asymmetry feature as a factor distinguishing rabeprazole from the comparators, emphasizing instead rabeprazole's particular 4-position substituent: "[T]he compound of the invention having a methoxy-propoxy at the 4' position of the pyridine ring . . . exhibits surprisingly unexpected [acid-]inhibitory effects . . . in comparison with closely related compounds of the type referred to by the examiner. Here attention is invited to item 5, page 3 of the examiner's letter where applicants have indeed compared the closest sulphonyl compound ethoxy methoxy with the claimed compound." (Id. at DRLRAB 466.) That specified item, Junggren Example 27, like the other two comparators referred to in the Fujisaki Declaration, bears a methoxyethoxy, instead of rabeprazole's methoxypropoxy, at the 4-position of its pyridine ring. (Id. at 470.)

Soon after, on April 3, 1991, Fan allowed the rabeprazole application to issue as patent '552. ('552 Patent File History, DRLRAB 473.) The patent's file history does not reveal why Fan ultimately decided that Eisai should receive the rabeprazole patent.

II. Prosecution of the Co-Pending Prosecution

On June 16, 1988, approximately seven months after filing the application for the '552 patent, Eisai via attorney Crawford filed the application for U.S. Patent No. 5,708,013 ("'013 patent"). ('013 Patent File History, DRLRAB 2281.) The '013 patent application listed the same 14 inventors as did the '552 patent application (P. Ex. 1, '552 Patent; P. Ex. 2, '013 Patent), and claimed inter alia a compound similar to rabeprazole in structure, prior art, and

asserted properties.[16] ('013 Patent File History, DRLRAB 2282.) Indeed, Eisai had written into its rabeprazole application a limitation purporting to exclude certain similar compounds – including the compound covered by the '013 application – from being considered as part of the '552 application.[17] ('552 Patent File History, DRLRAB 230-34.) Eisai prosecuted the two patent applications separately before different PTO examiners and, during some three years' overlap in the pendency of the two prosecutions did not disclose in either one the existence of, or any occurrences during, the other.[18] (See '552 Patent File History and '013 Patent File History for identities of different examiners and absence of disclosure.) There is no evidence that Fan knew of the '013 application, or that the examiners of that application knew of the '552 application.

The structure of the compound claimed in the '013 application differs from rabeprazole's by a single methylene unit (CH_2) at the 4-position of the pyridine ring. It there bears a methoxyethoxy ($OCH_2CH_2OCH_3$) substituent, where rabeprazole bears a methoxypropoxy ($OCH_2CH_2CH_2OCH_3$) substituent. The two compounds are otherwise structurally identical. (P. Mem., glossary at 7-8.) The similarity but for one methylene unit renders the two compounds homologous. Like defendants, the Court will refer to the compound claimed by the '013

---

[16] That similar compound was claim 8 of the original '013 patent application. ('013 Patent File History, DRLRAB 2343.)

[17] Without this affirmative exclusion, which the submissions sometimes refer to as a "proviso," the '552 application presumably could have been construed also to claim compounds sought in the other application.

[18] This Opinion addresses only those portions of the '013 patent application and its prosecution history that relate to the substance and prosecution of the rabeprazole application. The '013 patent application eventually was allowed, in an amended form excluding the compound here described as similar to rabeprazole, on January 13, 1998. (Killworth Decl. ¶ 87.)

application as the "ethyl homolog" of rabeprazole, after the ethyl segment that differs from rabeprazole's propyl segment.[19] (Teva R. 56.1 Stmt. ¶ 24.)

Eisai pursued both rabeprazole and the ethyl homolog for their gastric-acid inhibiting properties. (Teva R. 56.1 Stmt. ¶¶ 32-35, 49, for citations to contemporaneous acid-inhibition tests of both compounds by Eisai and to portions of the patent file histories of both compounds making similar assertions about their inhibitory properties). Eisai also made several identical, noteworthy representations in both prosecutions, for instance identifying Junggren and especially Junggren's omeprazole compound as prior art and reporting that both homologs showed "unexpectedly . . . potent inhibitory activity." (Id. at ¶¶ 48-49, for citations to comparable portions of the patent file histories of the two compounds).

A. First Rejection and Eisai's Response

On April 21, 1989, the PTO rejected the ethyl homolog claim (claim 8) of the '013 application pursuant to 35 U.S.C. § 102(b), that is, for lack of novelty – specifically, for being "anticipated by" the Juggren prior art reference, which also appeared in the '552 patent prosecution. ('013 Patent File History, DRLRAB 2471.) In the same action, the PTO rejected claims in the '013 application other than the ethyl homolog for being obvious in light of a combination of Junggren and either of two prior art references not mentioned in the '552 patent

[19] Eisai does not actually dispute the homologous relationship, but apparently protests this terminology's implication of similarity between the two compounds, for example by indicating that Teva's patenting expert deemed the two patent applications to be directed to "two different things." (P. Rule 56.1 ¶¶ 118, 123.) Such quibbles provide no reason why the Court should not take notice of the objectively evident homologous relationship between the two compounds. Nor does taking such notice entail finding the compounds to be identical. Indeed, there is no question that they are different (if only by one methylene unit): to be homologous is by definition to be similar but not exactly the same.

prosecution. One of these two references, which is significant to the issues in this case, is referred to by the parties as "Byk Gulden." (Id. at DRLRAB 2473.) The PTO rejection reads:

> The difference between the Junggren reference [and] applicant's claimed compounds [9, 13, and 17] is the trifluoromethyl group on the benzene ring of the benzimidazole. Both [Byk Gulden] and Rainer teach trifluor[o]methyl substitution of the benzene ring in similar compounds . . . . Since these compounds are all useful as gastric inhibitors and are all closely related in structure, one of ordinary skill would be motivated to combine the reference to produce applicant's compounds.

(Id.) This comment seems clearly to refer to claims other than the ethyl homolog, as the benzimidazole ring of the ethyl homolog – like that of rabeprazole – does not exhibit a trifluoromethyl substituent. (Compare diagrams of rabeprazole, the ethyl homolog, and Byk Gulden's "WO '646" compounds at P. Mem., glossary at 7-8.)

Eisai responded to the PTO's first rejection of the '013 application in much the same way it did to the first rejection of the rabeprazole application, namely by emphasizing the asymmetrical pyridine-ring substitution pattern of Eisai's claimed compounds and asserting superiority to omeprazole. On October 20, 1989, Crawford on behalf of Eisai narrowed the '013 patent application claims and argued:

> The outstanding [rejection] . . . cites and applies primarily Junggren . . . either alone as an anticipation of certain claims or combined with other references . . . . Junggren . . . contains identical substituents in the 3- and 5-positions . . . . By contrast, in the claims of the present application, the 5-position of the pyridine ring is always occupied by hydrogen (that is, it is unsubstituted), while the 3-position contains methyl.

('013 Patent File History, DRLRAB 2507; emphasis in original.) Also as in the rabeprazole prosecution, Eisai urged its claimed compounds' superiority to omeprazole in inhibiting gastric acid secretion. ('013 Patent File History, DRLRAB 2507-08.) Going beyond its rabeprazole

argument, however, in prosecuting the '013 application Eisai not only argued omeprazole's inferior efficacy but also its lack of asymmetrical substitution: "Note that omeprazole has a methyl group on both the 3- and 5-positions of the pyridine ring, [and] thus may be considered symmetrical in this regard." (Id. at DRLRAB 2508, emphasis in original.) Crawford further wrote, "Considering these structural differences and the associated differences (improvements) in gastric inhibitory activity as compared with even the preferred compounds of [Junggren] . . . the examiner will quickly appreciate the inventiveness and patentability of the claims now under review." (Id. at DRLRAB 2508-09.)

B. Second Rejection and Eisai's Response

These arguments failed to persuade the '013 application's examiners. On December 6, 1989, the PTO again issued a rejection. This time, the ethyl homolog claim, along with others, was specifically rejected "under 35 U.S.C. [§ 102(b)] as anticipated by or, in the alternative, under 35 U.S.C. [§] 103 as obvious over Junggren . . . in view of [Byk Gulden]." ('013 Patent File History, DRLRAB 2631.) Unlike the previous rejection, which had cited Byk Gulden in denying claims other than the ethyl homolog, this rejection clearly cited Byk Gulden – a prior art reference never volunteered by Eisai in either prosecution – directly regarding the ethyl homolog of rabeprazole.

The PTO's December 6, 1989, action also dismissed Eisai's asymmetrical-substitution argument, finding that the prior art actually revealed this feature. "Junggren . . . is not committed just to the symmetrical substituents. The generic formula discloses instant compounds by teaching asymmetrical substituents at the R^3 and R^5 positions. [Certain specified examples of Junggren] . . . all teach asymmetrical substituents at the R^3 and R^5 positions." ('013

Patent File History, DRLRAB 2631.) Junggren combined with Byk Gulden rendered the ethyl homolog claims unpatentable, the PTO determined, because "[Byk Gulden] discloses compounds which teach methoxyethoxy at the 4-position and methyl at the 3-position" – precisely the 3- and 4-position substituents of the ethyl homolog. (Id.) The rejection pointed to specific compounds in Byk Gulden that served to obviate Eisai's claims. (Id.) "One of ordinary skill in the art would be motivated to combine these references to produce the applicants' claimed compound," the rejection concluded. (Id.)

The PTO also cited yet another combination that rendered the ethyl homolog claims unpatentably obvious. Byk Gulden combined with another prior art application, Carlsson – which, as described above, the '552 patent examiner Fan had mentioned as a prior art compound of rabeprazole – taught asymmetrical substitution at the 3- and 5-positions and a methoxyethoxy substituent[20] at the 4-position, according to the PTO. ('013 Patent File History at DRLRAB 2632.) Eisai's data purporting to demonstrate the pharmacological superiority of the ethyl homolog claims over omeprazole were dismissed as "not . . . persuasive to overcome prima facie obviousness." (Id.)

Eisai tried again on June 6, 1990, with another submission responding to the second rejection of its '013 patent application. In this submission, Crawford sought to diminish the import of the prior-art teachings the PTO had cited, arguing that they were "broad" and "generic" and should not, in light of legal precedent, wholly preclude the patentability of later, more specific claims. ('013 Patent File History, DRLRAB 2646.) Eisai then asserted "evidence

[20] Although the examiner actually referred here to a "methoxylthoxy" substituent, it appears – both from the context of the statement and from a nearly illegible, tiny "e" handwritten into the word – that this is a typographical error for "methoxyethoxy."

of unexpectedly good inhibition of gastric secretion," as it had in the rabeprazole prosecution, as a basis for patentability. (Id.) Its response emphasized, again, the pyridine-ring substitution pattern: "The specific selection of the two substituents [methyl at the 3-position and methoxyethoxy at the 4-position] and [nonsubstituent] hydrogen on the pyridine ring provides the strong . . . gastric secretion inhibitory activity." (Id. at DRLRAB 2646-47.) Eisai then urged that Junggren and Carlsson did not disclose compounds featuring this pyridine-ring structure. (Id.) It did not address the PTO's Byk Gulden findings here, or at any point in either prosecution.

C. Final Rejection

On August 9, 1990, in a "final" action, the PTO rejected Eisai's arguments on behalf of the ethyl homolog claims. ('013 Patent File History, DRLRAB 2651.) Squarely countering Eisai's interpretations of Junggren and Carlsson, examiner Joseph McKane spelled out, "The prior art teaches methyl at the 3-position, hydrogen [i.e., nonsubstitution] at the 5-position, and methoxyethoxy at the 4-position." (Id. at DRLRAB 2651-52.) He concluded:

> The compounds in the prior art are used for inhibiting gastric acid secretion. Since the compounds of the prior art and the claimed compounds have the same utility and possess the same chemical and physical properties[,] it would have been obvious to one of ordinary skill in the art to produce applicants['] claimed compounds. Applicants have not overcome a prima facie case of obviousness. In [the] absence of unexpected or unobvious beneficial properties[,] the rejection would not be overcome.

(Id. at 2651.)

Eisai did not further pursue its claims to the ethyl homolog. As noted above, it pressed ahead instead with the rabeprazole application, which concluded successfully with the issuance of the '552 patent in April 1991.

PROCEEDINGS IN THE PRESENT ACTION

In August 2003, Defendants Teva and Reddy each filed an ANDA with the FDA, hoping to obtain approval to market generic rabeprazole-based products before expiration of Eisai's '552 patent. (Ds. Joint R. 56.1. Stmt. ¶¶ 7-8). The expedited-approval statute requires that applicants file a certification regarding the status of the already approved drug. See Yamanouchi Pharmaceutical, 231 F.3d at 1342 (describing statutory scheme). Defendants filed "paragraph IV" certifications, so known for the statutory subsection invoked, claiming that Eisai's patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug" proposed. (Ds. Joint R. 56.1 Stmt. ¶¶ 7-8, citing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).)

Eisai promptly filed these actions alleging patent infringement. Teva and Reddy have conceded infringement to the extent contemplated under the Hatch-Waxman regime. (Ds. Joint R. 56.1 Stmt. ¶¶ 9-11). Reddy has stipulated to the validity of the '552 patent. See Stipulation and Order, June 23, 2004, Docket No. 03 Civ. 9053 (GEL). Although Teva argues that the rabeprazole claims are invalid as obvious,[21] this Court has rejected that argument in a separate Opinion. See note 2 supra. Thus, the defendants' only remaining defense to be resolved in connection with this motion is their contention that Eisai engaged in inequitable conduct during prosecution of the '552 patent and should therefore be stripped of the right to enforce it. They charge, in brief, that Eisai committed inequitable conduct by intentionally and with respect to material information: (a) failing to disclose the co-pendency of, and rejections and substantive

[21] Conceding infringement does not preclude Teva from arguing invalidity, for, as Teva correctly points out, a claim held invalid cannot be found to be infringed. See Viskase Corp. v. Am. Nat'l Can Co., 261 F.3d 1316, 1323 (Fed. Cir. 2001) (citing Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1580 (Fed. Cir. 1983).

developments during, the similar '013 patent application, (b) misrepresenting by selective disclosure the patentability of rabeprazole's structure and properties, and (c) failing to disclose certain prior art.

Eisai now moves for summary judgment rejecting these charges and finding that plaintiffs did not engage in inequitable conduct.

LEGAL STANDARDS

I. Summary Judgment

Summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits . . . show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A "genuine issue of material fact" exists if the evidence is such that a reasonable jury could find in favor of the non-moving party. Holtz v. Rockefeller & Co., 258 F.3d 62, 69 (2d Cir. 2001). The moving party bears the burden of establishing the absence of any genuine issue of material fact. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986). In deciding a summary judgment motion, the court must "resolve all ambiguities and draw all reasonable references in the light most favorable to the party opposing the motion." Cifarelli v. Vill. Of Babylon, 93 F.3d 47, 51 (2d Cir. 1996). In addition, the court is not to make any credibility assessments or weigh the evidence at this stage. Weyant v. Okst, 101 F.3d 845, 854 (2d Cir. 1996).

The nonmoving party, however, may not rely on "conclusory allegations or unsubstantiated speculation." Scotto v. Almenas, 143 F.3d 105, 114 (2d Cir. 1998). The non-moving party "must do more than simply show that there is some metaphysical doubt as to the

material facts," Matsushita Elec. Indus. Co., Ltd., v. Zenith Radio Corp., 475 U.S. 574, 586 (1986), and must make a "showing sufficient to establish the existence of [every] element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

II. Inequitable Conduct

In attempting to perfect its claim to rabeprazole, Eisai, like all patent applicants, was required to demonstrate the novelty and nonobviousness of its claimed invention. 35 U.S.C. §§ 102, 103. It was also required to comply with all other rules and standards of patent prosecution. As patent prosecution is an *ex parte* process, and the PTO's investigative ability limited in time and resources, applicants seeking exclusive rights to an invention must fulfill a special obligation of candor and good faith to the PTO. Norton v. Curtiss, 433 F.2d 779, 793-94 (C.C.P.A. 1970). At the time of the disputed events, PTO regulations stated the duty, in pertinent part, thus:

> A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

37 C.F.R. § 1.56(a) (1987).[22] There is no exception to this principle. An applicant is subject to

[22] The Manual of Patent Examining Procedures ("MPEP"), promulgated by the PTO, sets forth practices to be followed by patent applicants and PTO processes of which they should be

the duty of candor even (indeed, especially) if making a disclosure would completely derail its prospects. A breach of this duty constitutes inequitable conduct and renders all claims of even a valid patent unenforceable. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995) ("Having determined that inequitable conduct occurred in the procurement of the '563 patent, all claims of that patent are accordingly unenforceable."); J.P. Stevens Co., Inc. v. Lex Tex Ltd., Inc., 747 F.2d 1553, 1559 n.4 (Fed. Cir. 1984) (where patent is held unenforceable because of applicant's inequitable conduct, "we need not and do not address the patent validity . . . issue[]").

To prove that inequitable conduct occurred in the prosecution of a patent requires showing clear and convincing evidence that the applicant affirmatively misrepresented or failed to disclose material information, or submitted false material information, with an intent to deceive the PTO. Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed. Cir. 2001). If a court decides that evidence of the disputed conduct supports a threshold inference of materiality and deceptive intent, it must then weigh that evidence against all other circumstances to determine whether conduct so culpable as to justify unenforceability has indeed occurred. Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). The Federal Circuit has held that where information withheld or misrepresented is proved highly material,

---

aware, pursuant to this duty of candor. While the MPEP does not constitute binding law, it has received judicial notice as an official interpretation of patent law. Litton Sys. v. Whirlpool Corp., 728 F.2d 1423, 1439 (Fed. Cir. 1984), overruled in part on other grounds by Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763 (1992). In an inequitable conduct dispute, moreover, the MPEP serves as a common articulation of patenting norms, indicating what information is appropriately considered material and reflecting on the intentions of an applicant who does not follow it. Thus, while a violation of standards set forth in the MPEP does not *ipso facto* constitute sufficient proof of inequitable conduct, courts appropriately take note of it as evidence on these subjects.

misconduct may be found on a lesser showing of intent – the inference being that, when information is so clearly related to a claim's patentability, its miscommunication can hardly be thought innocent.[23] See GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1275 (Fed. Cir. 2001) ("[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead.") (citation omitted); see also Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc., 438 F.3d 1123, 1134 (Fed. Cir. 2006).

A. Materiality

As the Federal Circuit Court of Appeals has done with patents prosecuted prior to the PTO's 1992 amendment of its rules, this Court here applies the judicially-adopted standard of materiality set forth in the pre-1992 version of 37 C.F.R. § 1.56, as quoted above.[24] Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1364 (Fed. Cir. 2003); cf. Purdue Pharma L.P., 438 F.3d at 1129 ("Because all of the patent applications at issue . . . were pending on or filed after March 16, 1992, we look to the current version of Rule 56, rather than the pre-1992 version of the rule"). The rule provides that "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56(a) (1987).[25]

---

[23] This principle would appear to be simply an application of the general rule that a party's intent may be proved by circumstantial evidence. The more clearly material information is, the more likely it is that the materiality of the information was perceived, and the more logical it is to infer that the failure to disclose it was intended to deceive.

[24] This Court need not and does not decide whether the analysis would differ under the new Rule 1.56(a). See 37 C.F.R. § 1.56(a) (amended).

[25] The Federal Circuit has never decided whether the standard for materiality in inequitable conduct cases should derive exclusively from the PTO rules or additionally from

Information might be clearly material, because it relates to novelty or obviousness. See 35 U.S.C. §§ 102, 103. Yet, while information such as obviating prior art may be quintessentially material, "[m]ateriality is not limited to prior art but instead embraces *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent."[26] GFI, Inc., 265 F.3d 1268 at 1274 (emphasis in original), citing Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380, 1382 (Fed. Cir. 1998); Dayco, 329 F.3d at 1363, citing Akron Polymer. Withheld

---

general equitable principles. Dayco, 329 F.3d at 1364. Certainly there is a lengthy history of federal courts' applying general equitable principles in the patent context. See, e.g., United States v. Am. Bell Tel. Co., 128 U.S. 315, 364-65 (1888) (describing the genesis of inequitable conduct in the patent context from the equity jurisprudence in real property law); Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814 (1945) (explaining that the court's authority to render patents unenforceable for inequitable conduct arises from the equitable principle that "he who comes into equity must come with clean hands."). At the least, courts have held those accused of inequitable conduct to the standard of the PTO rule. Nothing in this case requires the Court to decide whether a party may be held to have engaged in inequitable conduct under a broader standard than that in the rule.

[26] While the "reasonable examiner" standard clearly contemplates an objective inquiry, Eisai occasionally argues the immateriality of its nondisclosures based on what the particular '552 patent examiner herself knew or could have been presumed to know. For instance, Eisai submits that examiner Fan worked in the same "art unit" as those who examined the co-pending '013 patent application, that she had "exceptional experience," and that she, "unlike the '013 application examiners," had herself examined two prior-art applications defendants have alleged Eisai should have disclosed. (P. Reply Mem. at 26.) The argument ostensibly is that Eisai reasonably relied on, or reasonably assumed, Fan's subjective knowledge in withholding otherwise material information. This subjective standard finds no support in the case law. Indeed, such a standard would be inconsistent with the rationale of the affirmative disclosure duty, which is to place the onus of assembling material information on the one seeking to benefit rather than on the already burdened examiner. To the extent that Eisai cites Fan's subjective knowledge in an effort to disprove its deceptive intent – rather than immateriality of its nondisclosures – it has not made any showing sufficient to secure summary judgment. Even assuming that an applicant could exonerate itself by showing its awareness of evidence of a particular examiner's circumstances, numerous factual issues remain here: the record is hardly conclusive as to when Eisai became aware of Fan's purported knowledge and whether it relied on that supposed knowledge in good faith.

information, in other words, need not relate to a "but for" consideration of patentability in order to be held material.[27] See Li Second Family Ltd. v. Toshiba Corp., 231 F.3d 1373, 1380-81 (Fed. Cir. 2000) ("Information . . . may be material even though it would not invalidate the patent . . . . [T]he test for materiality is whether a reasonable examiner would have considered the information important, not whether the information would conclusively decide the issue of patentability.") Where an applicant is unsure of the materiality of any given information, it is "axiomatic that close cases should be resolved by disclosure, not unilaterally by applicant." GFI, Inc., 265 F.3d at 1274, citing LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 958 F.2d 1066, 1076 (Fed. Cir. 1992) (internal quotation marks omitted).

However, an applicant need not disclose even relevant information if that information is merely "cumulative," or, redundant – and thus, practically speaking, not material – in light of the existing record. GFI, Inc., 265 F.2d at 1274, citing Halliburton Co. V. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed Cir. 1991). It should be noted, though, that cumulativeness is a quite limited concept in this context. For instance, even if a certain combination of elements could be deduced from the existing the record by an examiner acting on her own, an applicant with knowledge of the combination nevertheless should disclose it. GFI, Inc., 265 F.2d at 1274 ("The [undisclosed] Durling references were not cumulative because no reference before the examiner disclosed this combination of required elements.").

[27] Of course, the likely effect of an item of information does go to its degree of materiality and, thus, to the plausibility of any inference of intent.

B. Deceptive Intent

Both materiality and intent are questions of fact, but in the sophisticated world of patent prosecution guilty applicants rarely leave "smoking gun" evidence of their deceptive intent. See Molins, 48 F.3d at 1180; Akron Polymer, 148 F.3d at 1384. Thus, courts often must infer intent where, after considering circumstances suggesting both bad- and good-faith conduct, the totality of evidence permits a "confident judgment that deceit has occurred." Akron Polymer, 148 F.3d at 1384; see GFI, Inc., 265 F.3d at 1274-75; Frazier v. Roessel Cine Photo Tech, Inc., 417 F.3d 1230, 1235-36 (Fed. Cir. 2005). The intent required for a finding of inequitable conduct is not merely a conscious and deliberate decision to withhold certain information, but also the intent specifically "to deceive or mislead the examiner into granting the patent." Therma-Tru Corp. v. Peachtree Doors Inc., 44 F.3d 988, 995 (Fed. Cir. 1995). However, where an applicant has actual knowledge of material information but fails to disclose it, such deliberate withholding may be circumstantial evidence of the required intent to deceive. See, e.g., GFI, Inc., 265 F.3d at 1274-75.

An even "strong[er] case for deceptive intent" may exist where an applicant not only knowingly withholds material information, but also "ma[kes] an argument for patentability that could not have been made had the [information] been disclosed." Id. at 1275. But, as already stated, even where it is merely found that undisclosed or misrepresented information is highly material, deceptive intent may be found without more, at least absent persuasive countervailing evidence of good faith. Id. The greater the materiality of the nondisclosure or misrepresentation, the easier to find culpable intent. Halliburton Co. v. Schlumberger Technology Corp., 925 F.2d 1435, 1439 (Fed. Cir. 1991).

C. Final Balancing

If a court finds evidence adequate to support a threshold inference of materiality and deceptive intent, it must then weigh that evidence against all other circumstances to determine whether the applicant's conduct was so culpable as to justify unenforceability. Baxter Int'l, Inc., 149 F.3d at 1327. The "challenged conduct must be sufficient to require a finding of deceitful intent in the light of all the circumstances." Akron Polymer,148 F.3d at 1383, citing Kingsdown Med. Consultants v. Hollister, Inc., 863 F.2d 867, 873 (Fed. Cir. 1988) (internal quotation marks and emphasis omitted).

Since patent prosecution by its nature entails selective presentation of information, it is easy enough for infringers to scatter defensive darts with the hope of hitting the inequitable-conduct bull's-eye. Eisai accordingly urges this Court closely to police this "absolute plague" of an affirmative defense. (P. Mem. at 17, citing Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988).) Caution is warranted. Courts have noted that inequitable conduct is a defense frequently raised, but not often proved, and have urged restraint in applying a defense that prevents enforcement of a valid patent. See, e.g., Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co., 732 F.2d 903, 908 (Fed. Cir. 1984); Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1454 (Fed. Cir. 1984); Burlington Indus. Inc., 849 F.2d at 1422. Nevertheless, where a charge has true aim and pinpoints provably culpable conduct, courts must in the interest of fairness strip the patent-holder of its ill-gotten exclusive right. Indeed, while defendants lodge numerous allegations of inequitable conduct, ultimate proof of just one will suffice to render the '552 patent unenforceable. See GFI, Inc., 265 F.2d at 1275 ("Because the failure to disclose the Durling references alone supports unenforceability of the

claims of the '244 patent, we need not address the remaining references.").

At this stage in the proceedings, however, the Court is faced not with deciding after a full trial whether inequitable conduct has been proved, but with the quite different inquiry whether Eisai may win summary judgment that no inequitable conduct occurred. Eisai bears the burden of showing the lack of any issue of material fact as to each claim of inequitable conduct. Eisai is entitled to summary judgment only if it appears on the existing record that no reasonable factfinder could find by clear and convincing evidence – after a trial where credibility may be weighed and witnesses cross-examined – that Eisai committed inequitable conduct.

DISCUSSION

I. Nondisclosure of the Co-Pending Patent Application

Defendants argue that summary judgment is precluded by their evidence relating to Eisai's co-pending application for rabeprazole's homolog. Defendants urge that information about the ethyl homolog application would have been important to rabeprazole's examiner from the very moment it was filed, but that such information became especially material to rabeprazole's fate once rejections in the co-pending application began to issue. They charge that Eisai deliberately and repeatedly failed to inform Fan about the ethyl homolog application, even as developments suggested its increasing materiality, and that Eisai thus engaged in inequitable conduct.

Eisai's efforts to negate the existence of genuine issues of material fact as to the wrongfulness of its nondisclosures of the co-pending ethyl homolog application entirely fail. Defendants offer a sufficient showing upon which a reasonable factfinder could, by the requisite clear-and-convincing standard, deem Eisai culpable of inequitable conduct on these grounds.

A. Fact of Co-Pendency

Defendants allege that the mere fact of the ethyl-homolog application's concurrent existence was information that a reasonable examiner would have considered important to know in deciding whether to grant the same applicant a patent for rabeprazole. They argue that the two compounds were "patentably indistinct" and that the rabeprazole examiner – had she known about the co-pending ethyl homolog claims – could at the least have issued a "provisional" double-patenting rejection to avoid bestowing duplicative patent rights on Eisai. Given the compounds' close similarity and the prohibition against double-patenting, defendants charge, Eisai knew or should have known to disclose the co-pendency of the '013 application in its '552 patent prosecution. Defendants further contend that deceptive intent may be inferred from the clear materiality of the undisclosed fact. (See Teva Mem. 18-24; Reddy Mem. 24-31.)

Both PTO rules and case law discourage the granting of duplicative patent rights not just as between different applicants – to protect an owner's exclusive right – but also as to a single applicant, to avoid over-protecting that right. In the period relevant here, the MPEP stated that "if an inventor has different applications pending in which similar subject matter but patentably indistinct claims are present that fact must be disclosed to the examiner of each of the involved applications." M.P.E.P. § 2001.06(b)(1986). Patent examiners were instructed to issue "provisional" double-patenting rejections in such overlapping applications, essentially raising an internal flag that substantially similar claims were in play. (Stoner, Decl. 1 ¶¶ 90-91; Smith Decl. ¶¶ 85.) The rationale for these rules, as has been recognized by the courts, was to avoid granting overextensive ownership periods or multiple transferrable interests regarding substantially similar claims. Dayco, 329 F.3d at 1365-66; Akron Polymer,148 F.3d at 1382; In

re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985). In affirming the PTO's denial of certain claims for asserting "the same invention [as another application] or an obvious modification thereof," the Federal Circuit has explained that the worry is not just private wrongdoing but public harm: "[T]he maintenance of a patent that creates double patenting is . . . an imposition on the public." In re Lonardo, 119 F.3d 960, 965-66 (Fed. Cir. 1997), citing, e.g., In re Longi, 759 F.2d at 892.

Hence, the Federal Circuit in Dayco Products, Inc. v. Total Containment, Inc. – addressing a summary judgment ruling that a patent-holder had engaged in inequitable conduct partly by failing to disclose a "substantially similar" application also prosecuted in its name – held that, where "disclosure of the [other, commonly owned] application . . . could have led to double patenting rejections in the applications that issued as the patents-in-suit . . . . the pendency of [that other] application was, therefore, material." Dayco, 329 F.3d at 1361, 1365-65. The court mentioned MPEP § 2001.06(b) but also invoked the relevant judicial standard of disclosure: "This court has held that under the 'reasonable examiner' standard of materiality, an application was highly material to the prosecution of an application where it could have conceivably served as the basis of a double patenting rejection." Id. at 1365 (citation, internal brackets, and quotation marks omitted).

Defendants do not merely argue that the ethyl homolog was similar enough to rabeprazole that it could conceivably have triggered a double-patenting rejection of rabeprazole. Rather, they argue – seemingly to accord with the MPEP language – that the two compounds were "patentably indistinct" as a matter of law, because they shared "very close structural similarities and similar utilities [and], without more [were] . . . prima facie [obvious]." (Teva Mem. 19, citing In re Grabiak, 769 F.2d 729, 731-32 (Fed. Cir. 1985) (internal quotation marks

omitted); Reddy Mem. 25.) Eisai objects to defendants' characterization of the disputed compounds as "patentably indistinct," denying that the compounds presented the prima facie case of obviousness.[28] (Eisai Reply. Mem. 24.) Indeed, the Federal Circuit in In re Grabiak, et al., upon which defendants rely for their prima facie obviousness argument, cautioned that "generalization should be avoided insofar as specific chemical structures are alleged to be *prima facie* obvious one from the other." 769 F.2d at 731. In that case, the PTO's rejection was reversed when appellant showed that the application for the purportedly obviating compound did not contain the necessary teachings to make the alteration toward the challenged compound. Id. The Court reversed the PTO's prima facie obviousness determination, because "one of ordinary skill in the art" would not have been motivated to produce the disputed compound based solely on the existing art. Id. at 732.

At this stage, however, it is not necessary to resolve whether the two compounds were, in fact, patentably indistinct. Nor is it clear that this is the showing defendants would have to make at trial, to sustain an inequitable conduct judgment by the judicial standard. While the Dayco court incorporated the label in its mention of the MPEP procedure, the contested applications there were actually dubbed "substantially similar." 329 F.3d at 1361. The court held material the existence of undisclosed claims that "were in some respects substantially identical to the claims of the patents-in-suit," without declaring one way or the other that the claims were patentably indistinct. Id. at 1361. See also McKesson Information Solutions, Inc. v. Bridge

---

[28] Eisai also responds by arguing that "double patenting is not a *prior art* obviousness rejection under 35 U.S.C. § 103." (Eisai Reply Mem. 24, emphasis added.) Lack of elaboration renders the argument unclear, but to the extent that Eisai argues double-patenting to be a concern only as between applications and separately owned prior art, the case law, stated supra, clearly shows Eisai is wrong. The concern is also with issuing duplicative patents to a single owner.

Medical, Inc., 02 Civ. 2669 (FCD), 2006 WL 1652518, at *18 (E.D. Cal. June 13, 2006) ("Beyond meeting the Dayco 'substantially similar' test, the two rejections . . . are material for [an] independent reason," finding inequitable conduct partly based on patentee's unjustified failure to disclose rejections in a co-pending, similar prosecution). For now, it is unnecessary to pinpoint the precise degree of similarity required, for to survive summary judgment defendants need only show that a genuine issue of material fact exists as to the substantial likelihood that rabeprazole's examiner would have wanted to know of the '013 patent application's co-pendency for the purpose of precluding overlapping patents. If a reasonable factfinder could conclude that the information is sufficiently material, defendants will also have shown enough to raise an issue as to Eisai's intent in not disclosing.

Eisai has failed to show the absence of a genuine issue as to the patentable indistinctness, or substantial similarity, of the two compounds. Besides conclusorily stating that "the rabeprazole and ethyl homolog claims do not overlap" and are "different" (P. Reply Mem. 25), Eisai offers little to deny that the nearly identical claims were anything other than mutually obviating.[29] The only possible evidence to that end is Eisai's specific mentions of rabeprazole's methoxypropoxy substituent in arguments to examiner Fan, which could be construed as distinguishing the two homologs by their sole differing feature. But those submissions did not address the ethyl homolog at all and cannot conclusively prove, without more, that the difference of the single methylene unit of rabeprazole served to render it patentably distinct from the ethyl

[29] Indeed, for all its protestations against finding the compounds prima facie obvious in light of each other, Eisai has not suggested that a person of ordinary skill in the art in possession of the rabeprazole application could not, without more, have created the ethyl homolog, or vice versa.

homolog. Teva notes that Eisai patenting head Taniguchi knew the separately claimed compounds were quite similar, and that he testified, "[O]ne was rabeprazole and the other was a derivative of rabeprazole . . . a related derivative." (Teva Mem. 19, 34; see also Taniguchi Dep. 37:22-38:12; 77:3-25.) Teva's expert opines that the pharmacological data offered in both applications showed the compounds to be functionally, not just structurally, similar. (Forte Rep. ¶ 55.) While Eisai's patenting expert testifies that the ethyl homolog application was "substantially more abbreviated" than the rabeprazole application – for instance, in its lack of in vivo animal data – he does not assert with any specificity that the applications were patentably different.[30] (Killworth Decl. ¶ 74.) Evidence of Eisai's unilateral "proviso" limitation, purporting to exclude the ethyl homolog compound from the '552 patent application, does not negate the question whether this action sufficed meaningfully to differentiate the claims.[31] The '013 and '552 patent applications otherwise shared numerous, significant similarities.

Indeed, Eisai does not waste much effort disputing that the claims were so similar that examiner Fan could have issued, as defendants allege, a "provisional" double-patenting

---

[30] Eisai only begs the question with its submission that Crawford, its patent attorney, "testified that the mere fact that [the compounds] were homologs was not sufficient for him to conclude that they were patentably indistinct." (P. Reply Mem. 24.) His testimony may go to negating intent, but the basis for finding one application material to another – and thus disclosable – depends not on the accused patent prosecutor's subjective views, but on those of the reasonable examiner.

[31] Eisai's patenting expert, Killworth, insists that there is "no question that the 'proviso' language in the original '552 patent application [purporting to exclude the ethyl homolog] . . . clearly meant that the claims of the '013 and '552 applications were different." (Killworth Decl. ¶ 101.) But this proviso hardly saves Eisai. To the contrary, use of such a proviso seems the very kind of act – selecting out one subset of claims from a larger set, to pursue a second application – that raises concerns that an applicant may unfairly obtain two patents based on one substantially similar set of claims. The law does not leave it to the applicant to conclude that its precautions have avoided a double-patenting problem.

rejection.[32] (P. Mem. 37.) Instead, it protests that a "provisional" rejection is so insignificant an occurrence in the process of patenting that information withheld cannot be found material on this ground. Only when a co-pending application is actually granted – and a "provisional" double-patenting rejection thus transformed into a "real" one – Eisai argues, can its existence become material to the patentability determination of the other application.[33] (Id., arguing that "[a] 'provisional rejection' is not a 'rejection.'") In this vein, Eisai's expert Killworth testifies that "'double patenting' is based on the claims of the patent as they are *issued*, and not the claims of a patent *application*." (Killworth Decl. ¶ 93, emphases added.) In other words, only if the ethyl homolog claims had actually issued, and issued first, does Eisai believe it might have had the duty to inform rabeprazole's examiner about the other application.

Pointing to the Dayco case, Eisai insists that the Federal Circuit has never "discuss[ed] or analyze[d] whether a 'provisional' double patenting rejection would have been important to patentability." (P. Mem. 38; see also P. Reply Mem. 19.) It is true that the word "provisional" does not appear in that case. Yet that decision rests nothing on the actual issuance of substantially similar patents, stressing rather the patent prosecutor's duty to disclose any

---

[32] Teva goes so far as to submit that "Eisai *concedes* that a double patenting rejection *would have* issued in the rabeprazole application." (Teva Mem. 21.) However, as Eisai's briefing argues precisely the opposite, (see, e.g., P. Mem. 37), the Court does not assume such a concession.

[33] The Court construes Eisai's arguments dismissing the significance of "provisional" patents as an attempt to distinguish *potential* double-patenting rejections from *actual* ones. To the extent that Eisai could be taken to argue that the word "provisional" itself holds dispositive legal significance, the Court rejects such an effort as completely meritless. Eisai cites no authority for treating a "provisional" rejection as anything less than an internal PTO vehicle for pursuing the judicially recognized policy of avoiding issuance of two substantially similar patents – i.e., as a *potential* double-patenting rejection.

information that "*could have* led to double patenting rejections in the applications that issued as the patents-in-suit." Dayco, 329 F.3d at 1365 (emphasis added). A "basis for establishing unpatentability is [a] *potential* double patenting rejection," the Court held. Id. at 1366 (emphasis added). Notably, the court's discussion focused on the materiality of a "*co-pending*" similar *application*, not of an *already-issued* similar *patent*.[34] Id. at 1362 (emphases added); see also id. at 1365-66 (where "disclosure . . . *could have* led to double patenting rejections in the applications that issued as the patents-in-suit . . . . the *pendency* of [that other] application was, therefore, material") (emphases added). Eisai's own patenting expert testified that PTO examiners take the time to check for the *co-pendency* of similar applications before deciding to issue a patent – indicating that such information is indeed important for a reasonable examiner to know. (Killworth Decl. ¶ 68, noting that examiner Fan before issuing the '552 patent conducted an "Interference Search," a step which is meant to turn up "co-pending applications claiming the same or obvious variations of the subject matter of the application at issue.")

Eisai's attempt to rely on the fortuitous, hindsight observation that the homolog claims never were approved – and that the rabeprazole claims therefore did not actually issue as a duplicative patent – would seem to turn the rationale of the disclosure duty on its head.[35] As

---

[34] Indeed, of an already issued patent, there would not be much to discuss: If the earlier issuance of another, substantially similar patent to the same applicant is *not* per se material to a subsequent application, it is difficult to imagine what would be.

[35] The accused in Dayco attempted a similar argument, that "information material at the outset of prosecution may become immaterial depending on the result of the prosecution." 329 F.3d at 1365. But the patent-holder there had preemptively taken a curative step it would have had to, to save its claims, in the event of an actual double-patenting rejection – specifically, limiting the term of the disputed patent to the same period as that of the nondisclosed, conflicting claims. Id. at 1365. Even so, the court expressly declined to decide whether such unilateral curative measures could overcome a subsequent charge of inequitable conduct. Instead, it found

discussed, the duty covers not only "but for" considerations of patentability, but also less certain ones. There is no exception permitting applicants to withhold material information and avoid accountability if events happen to unfold in their favor. There is no question that the law discourages issuance of duplicative patents. Eisai's submission that the rabeprazole examiner checked on her own for overlapping claims not only is irrelevant to deciding whether Eisai fulfilled its affirmative disclosure duty by the objective standard,[36] but also serves to underscore the materiality of the information Eisai did not disclose. Also irrelevant is Eisai's argument that a "provisional" rejection is unimportant because Eisai would not have had to respond to it (P. Mem. 37), as materiality is not measured by the degree of associated applicant effort. Even if a "provisional" rejection would have been lifted as a matter of course the moment the '552 patent claims were approved, as Eisai insists (id.), the law of inequitable conduct and of double-patenting counsels that the rabeprazole examiner should have been given the opportunity to make that decision. Eisai has hardly negated the existence of a triable issue as to whether the co-pending applications so resembled each other that a reasonable examiner of the rabeprazole claims would have wanted to know about the co-pending application to avoid issuing a duplicative patent.

---

nondisclosure of the co-pending claims material because of a different possible consequence of double-patenting, which the accused had not attempted to cure: the requirement of a common-ownership limitation on overlapping patents. Id. Eisai does not represent that it independently neutralized all possible double-patenting consequences.

[36] Eisai does not suggest that it *knew* of Fan's "Interference Search" and that it relied on this knowledge – whether properly or not – in not disclosing the co-pending claims. Eisai's further submissions about Fan's subjective expertise and circumstances (P. Reply Mem. 26) are also, for the same reasons, irrelevant to assessing both materiality and intent.

Nor has Eisai proved the lack of a genuine issue as to its intent in not disclosing the co-pendency of the '013 patent application to the rabeprazole examiner. Besides disputing the materiality of the information, Eisai submits that its patent attorney and others involved in the '552 patent application simply did not believe that their disclosure duty covered information from a "later-filed" application. (P. Reply Mem. 20; P. Mem. 43-44; Killworth Decl. ¶ 101.) Plaintiffs do not counter defendants' argument (see, e.g., Teva Mem. 33), that, at the least, Eisai was put on notice of a potentially important overlap between the separate applications claiming homologs when Fan wrote in her first rejection of rabeprazole, "[prior] art compounds are homologs of the claimed compounds rendering the claimed compounds unpatentable." ('552 File History at DRLRAB 292-93.) Eisai instead protests that "there is no allegation that Eisai tried to 'steer' the '013 patent application to a different examiner from the rabeprazole application." (P. Reply Mem. 26.) But such "smoking gun" evidence of deception is not required. A reasonable factfinder need not accept protestations of ignorance where the materiality of the nondisclosure is great. Here, Eisai has neither diminished the degree of materiality nor offered exonerating evidence such that a reasonable factfinder could not infer that it intended to deceive rabeprazole's examiner by withholding the fact of the '013 patent application's co-pendency.

Case law strongly supports the conclusion that the failure to disclose material co-pending applications is powerful evidence of intent to deceive. The patentee in Dayco only escaped summary judgment of inequitable conduct by showing that it had actually disclosed the fact of co-pendency in one of the concurrent prosecutions. The court there ruled that the disclosure in one application left at least a triable issue as to the accused's intent to deceive the PTO. 329

F.2d at 1366. Similarly, in Akron Polymer, the Federal Circuit reversed a finding of deceptive intent based on applicant's failure to disclose the co-pendency of similar applications, because the applicant had actually disclosed in one of the prosecutions. That disclosure "point[ed] away from an intent to deceive," the court concluded. 148 F.3d at 1384. However, it cautioned that, "[b]ut for the fact that [the accused] actually disclosed the fact of copendency of the two applications to the PTO . . . it could be argued that the other facts in this case are sufficient to support a threshold finding of deceitful intent by clear and convincing evidence." Id. Those "other facts" showed that "the same law firm and the same attorneys prosecuted both applications, and that those attorneys were aware of the similarity of the inventions disclosed in the two applications . . . . [and of] the possible consequences should the PTO find the inventions not patentably distinct." Id. at 1383. Eisai has not offered any proof that it disclosed co-pendency in either the '013 or the '552 application process, nor any proof that the two applications were significantly different. Under such circumstances, a reasonable factfinder could find intent to deceive.

B. Rejections

Defendants in this case do not rely merely on the non-disclosure of the fact of the '013 patent application's co-pendency, but also on Eisai's failure to disclose the rejections that ensued in that prosecution during consideration of the rabeprazole claims. Assuming the close similarity between the ethyl homolog and rabeprazole, defendants argue that the mere issuance of a rejection of one substantially similar claim is per se material to the co-pending prosecution of another. Further, they urge that the substantive reasons provided in the ethyl homolog's rejections were themselves material to the rabeprazole application, arguing that Eisai should

have disclosed these reasons because they were directly material to the rabeprazole application.

1. "Per Se Materiality"

Defendants again point to Dayco, which holds in part that "a contrary decision of another examiner reviewing a substantially similar claim meets the . . . [pre-1992] 'reasonable examiner' threshold materiality test of '*any* information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.'" 329 F.3d at 1368 (quoting Akron Polymer, 148 F.3d at 1382) (emphasis in original). They argue that, under Dayco, any rejection "of substantially similar claims . . . in a co-pending application" is "*per se* material to the examination of the other application." (Reddy Mem. 32; see also Teva Mem. 24, 26.) That court explained the logic of its holding:

> Patent disclosures are often very complicated, and different examiners with different technical backgrounds and levels of understanding may often differ when interpreting such documents. Although examiners are not bound to follow other examiners' interpretations, knowledge of a potentially different interpretation is clearly information than an examiner could consider important when examining an application.

329 F.3d at 1368.

Eisai counters that it cannot be held to the "per se" materiality standard defendants advance because no such legal rule existed at the time of the rabeprazole prosecution. It correctly indicates that the Dayco court itself noted that it had "never addressed whether the prior rejection of a substantially similar claim in a copending . . . application is material under the reasonable examiner standard." (P. Reply Mem. 21, citing 329 F.3d at 1367.)

This argument is unpersuasive. First, as noted by the district court in McKesson Information Solutions, "[t]he principle requiring disclosure of material events during

prosecution, including rejections, had been recognized prior to Dayco." 2006 WL 1652518, at *17, citing Li Second Family, 231 F.3d at 1380-81 (affirming inequitable conduct judgment based in part on failure to disclose decision of PTO Board of Appeals in co-pending application) and Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., 837 F.Supp. 1444, 1474 (N.D. Ind. 1992) (finding inequitable conduct based on failure to disclose rejection in co-pending case). Second, whether or not the Federal Circuit had authoritatively proclaimed certain information to be *automatically* material at the time these patents were prosecuted does not affect whether the disputed information was *in fact* material, but goes at most to mitigating Eisai's intent. And even on that point, Eisai's argument is hardly dispositive: while a reasonable fact-finder would no doubt be more likely to find deception where a patent prosecutor withheld a type of information already deemed material by well known precedent, a factfinder is not limited to finding deceptive intent only in cases where such precedent exists.

2. Materiality of the Junggren Reference

In any event, defendants have demonstrated the existence of genuine issues as to the materiality of the *reasons* underlying the ethyl homolog rejections and as to Eisai's intent in failing to disclose them. First, defendants allege that Eisai wrongly failed to disclose the observation – made in two PTO rejections of the ethyl homolog claims while the rabeprazole application was pending – that prior-art compounds from Junggren taught the asymmetrical 3- and 5-position pyridine-ring substitution pattern that Eisai had pointed out to examiner Fan in its response to her first rejection of rabeprazole. (Reddy Mem. 33; Teva Mem. 25-26.) Teva insists that this observation was "highly material," because Eisai had argued for rabeprazole's patentability by noting that certain Junggren compounds were symmetrically substituted, in

contrast to the claimed compounds. (Teva Mem. 25; see '552 Patent File History, DRLRAB 429.) Reddy similarly argues, "It doubtless would have been important to a reasonable examiner of the [r]abeprazole [a]pplication to know that [ethyl homolog's] Examiner McKane had specifically rejected applicants' characterization of Junggren." (Reddy Mem. 33.)

Eisai denies materiality by protesting that its March 1989 submission to Fan about the Junggren compounds' symmetrical substitution pattern was not an argument for rabeprazole's patentability but rather a "brief assertion," which Fan in her second rejection said she "did not understand" and thus "dismissed." (P. Mem. 42-43; for facts of Fan's comments and possible interpretations of them, see supra, note 13, and accompanying text.) It offers its patenting expert's analysis of that March 1989 submission, which indicates that Eisai was promoting rabeprazole not based on its asymmetrical pyridine-ring pattern, but on showings of its "unexpected [pharmacological] properties." (Killworth Decl ¶ 57.) Moreover, Eisai argues, Fan already had general knowledge of the Junggren prior art, and examples of asymmetrical substitutions were evident in that prior art. (P. Mem. 43; Killworth Decl. ¶¶ 113-24, testifying, "Examiner Fan could read the Junggren '431 patent for herself and fully understand its contents . . . . The Junggren '431 patent has numerous 'asymmetric' examples that are plainly apparent in [disclosed tables].")

Eisai's submissions fail to negate the existence of genuine issues as to the materiality of the undisclosed observations by the '013 patent examiner about Junggren. A reasonable factfinder need not accept Eisai's expert's interpretation that Fan "dismissed" Eisai's asymmetry assertion when she stated that it was not understood. (Killworth Decl. ¶ 60.) Eisai's response to Fan's first rejection nowhere alerts the examiner that some portion of its argument is not relevant

to the case for patentability, but merely a meaningless digression. ('552 Patent File History, DRLRAB 427-434.)[37] Moreover, as set forth above, there is considerable evidence from the '013 patent prosecution that Eisai believed and argued pyridine-ring asymmetry to be a patentable feature of rabeprazole's homolog. While those representations cannot by themselves prove the significance of Eisai's asymmetry comment in the '552 patent application, a reasonable factfinder could draw inferences from them adverse to the credibility of Eisai's current claim that the distinctiveness of asymmetric substitution was not a major part of its argument to Fan about the patentability of rabeprazole.

Nor is Eisai's interpretation of Fan's rejection indisputable. Defendants' expert reads Fan's ambiguous comment as meaning that Eisai's argument about asymmetry was "not understood" in light of the continuing presence, at that time, of symmetrically-substituted compounds in the '552 patent application. (Teva R. 56.1 Stmt. ¶ 64; see note 13 supra and accompanying text, for facts relevant to the differing interpretations.) That reading is as plausible as plaintiffs'. Indeed, the fact that Fan repeated her "not understood" comment in a subsequent rejection and only issued the '552 patent after Eisai had narrowed its claims to the asymmetrically-substituted rabeprazole, would tend to support defendants' reading. It is far from clear, on this record, that Fan was not prompted by Eisai's "brief assertion" to consider

---

[37] Defendants submit expert testimony casting further doubt on Eisai's argument:

> It appears nonsensical to read [Eisai's asymmetry remark] as anything other than an argument to persuade the examiner that the examiner's rejections were unwarranted . . . . Nor would a reasonable examiner have read the language as anything other than an argument for patentability setting forth structural distinctions over the prior art.

(Stone Decl. 2 ¶ 36.)

rabeprazole's pyridine-ring substitution pattern to be a patentable aspect; the file history does not reveal the actual reasons for Fan's final decision. If that is so – and a reasonable factfinder could certainly so conclude on this record – then a triable issue of fact exists as to whether a reasonable examiner of the rabeprazole claims would have wanted to know about rejections in a substantially similar application partly based on Junggren's teaching of asymmetry.

3. Materiality of the Byk Gulden reference

Another material aspect of the undisclosed ethyl homolog rejections, defendants charge, is their revelation of the Byk Gulden prior art reference. The PTO cited this reference, which never came up in the '552 patent prosecution, in all three rejections of the '013 patent application.[38] The December 6, 1989, rejection deemed the ethyl homolog to be unpatentable – on alternative grounds of obviousness or lack of novelty – in light of Byk Gulden as combined with either of two prior-art references that also appeared in the rabeprazole prosecution, Junggren and Carlsson. The combination with Junggren taught asymmetrical substitution of the pyridine ring with a methoxyethoxy substituent at the 4-position and a methyl at the 3-position, the PTO explained, while the combination with Carlsson also taught asymmetry and a methoxyethoxy substituent at the 4-position. In the final, August 9, 1990, rejection of the ethyl homolog claims citing Byk Gulden, the PTO stated that "the compounds of the prior art and the claimed compounds have the same utility and possess the same chemical and physical properties." ('013 Patent File History, DRLRAB 2651.) Eisai received all of these rejections while the rabeprazole claims were still pending.

[38] Eisai correctly points out that the first rejection cited Byk Gulden with respect to claims *other than* the ethyl homolog. (P. Reply. Mem. 21-22.)

Defendants urge that the rejections raising Byk Gulden were "highly material" to the rabeprazole prosecution, because they expressed in one shot that the prior art taught a combination of two features – asymmetrical pyridine-ring substitution with a 4-position methoxyethoxy substituent – that "undermin[ed]" Eisai's arguments about rabeprazole's distinctiveness. (Teva Mem. 27-28; Reddy Mem. 33.) Eisai counters that Byk Gulden would have been merely cumulative and thus not material to the rabeprazole examiner, because a compound it had disclosed, from the Beecham prior art reference, displayed the same asymmetrical substitution pattern with an alkoxy substituent. (P. Mem. 31, showing diagrams of rabeprazole and Example 7b of Beecham.) It argues that the Beecham compound more closely resembles rabeprazole than do the relevant Byk Gulden compounds, because the latter feature substitution on their benzimidazole rings while the former, like rabeprazole, do not. (P. Mem. 29-31, see id. 29 for diagram of Byk Gulden compounds.) Defendants counter that the '552 patent application – until the January 1991 amendment, which post-dated the relevant ethyl homolog rejections – encompassed compounds with benzimidazole substituents like those of the Byk Gulden compounds. (Teva Mem. 29, n.26.) They also argue that the 4-position pyridine-ring substituents of rabeprazole and the Byk Gulden compounds – alkoxy groups differing by only one methylene unit – render those more materially similar to each other than rabeprazole is to the Beecham compound. (Teva Mem. 30.) The parties also greatly dispute to what extent, if at all, the benzimidazole ring mattered in patent applications to proton-pump inhibiting compounds. (See P. Mem. 32; Teva Mem. 30, n.27.)

Defendants further argue that the Byk Gulden-based rejections were material for a still more significant reason than the substitution pattern of its pyridine ring: Byk Gulden was the

only prior-art reference that specifically taught the use of a methoxypropoxy 4-position substituent. (Teva Mem. 30; Reddy Mem. 34.) Eisai repeatedly highlighted this particular feature of rabeprazole in its submissions to examiner Fan – at one point indicating it was a basis for "novelty" – and thus rendered any contradictory information material, defendants urge. (Teva Mem. 28.) While the ethyl homolog rejections from the relevant period do not specifically mention methoxypropoxy, defendants presumably – although not explicitly – aver that Fan, if alerted to the substance of the ethyl homolog rejections, could have uncovered this detail of Byk Gulden on her own. Such a discovery could have formed the basis of an obviousness rejection of rabeprazole, defendants allege. (Teva Mem. 28.)

Eisai does not dispute that Byk Gulden teaches a methoxypropoxy at the pyridine ring's 4-position, but it protests that the prior-art disclosure encompasses "over *30 billion* possible compounds." (P. Mem. 34, emphasis in original.) It charges that it is "pure hindsight for [defendants] to create a compound by starting with rabeprazole and making numerous choices out of the multiple paths possible in this enormous disclosure." (Id.; see id. at 33 n.23 for undisputed description of Byk Gulden's methoxypropoxy disclosure.) Moreover, Eisai points out, Byk Gulden does not offer examples of any actual proton-pump inhibiting compounds featuring a methoxypropoxy at the 4-position of the pyridine ring, but merely discloses the possibility of the substitution. (Id. at 34-35; P. Reply Mem. 12-13.) Defendants do not dispute this characterization. Further, Eisai uncontestedly submits that the '013 patent application examiners did not themselves identify Byk Gulden's specific mention of methoxypropoxy until 1996, after Eisai had elected to exclude the ethyl homolog from that application's claims and many years after the '552 patent had issued. (P. Mem. 36, citing Killworth Decl. ¶¶ 84-86; see

also '013 Patent File History, DRLRAB 2756.) Presumably Eisai's argument against materiality is that the methoxypropoxy teaching is so indiscernible from mere knowledge of Byk Gulden's existence that learning of her colleague's citation of Byk Gulden would not have been important to rabeprazole's examiner on this ground.

These disputes are essentially questions of fact for trial. Whether and to what extent Byk Gulden would have presented material information to a reasonable examiner – whether because it combined in one place prior art that otherwise needed to be assembled from disparate sources, or because it uniquely disclosed a key patentable feature of rabeprazole – are questions implicating the drawing of inferences and the credibility of the parties' experts, and are not suitable for resolution by summary judgment. Eisai may well be correct that Byk Gulden's disclosure of the 4-position methoxypropoxy substituent was so deeply buried in a teaching of billions of compounds that a reasonable examiner of rabeprazole would not have uncovered it merely from knowing the content of the ethyl homolog rejections. On the other hand, the fact that the '013 patent application examiners eventually did unearth the methoxypropoxy disclosure, albeit not until 1996, tends to support the inference that the rabeprazole examiner could have uncovered it. Clearly there remain genuine issues of material fact as to the importance of the Byk Gulden-based, ethyl-homolog rejections to the rabeprazole application.

4. Deceptive Intent

Eisai also fails to demonstrate the absence of genuine factual issues as to whether it withheld the fact or substance of the ethyl homolog-related rejections with an intent to deceive the rabeprazole examiner. In support of its claim of good faith, Eisai relies principally on testimonial evidence from the very actors who bore the duty of candor on its behalf. For

instance, plaintiffs submit that "Eisai's U.S. attorney at his deposition did not recall believing that the Byk Gulden . . . patent was important to the rabeprazole application." (P. Mem. 35, citing P. Ex. 81, Crawford Tr. 390:12-391:5. 423:9-424:4, 426:14-430:7.) Such protestations need not be accepted by the factfinder. The professed ignorance of the applicant's prosecuting attorney, or testimony of the applicant's internal misunderstandings or miscommunications, is not conclusive proof of innocence. See Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp, 424 F.3d 1347, 1361-62 (applicant may not avoid a charge of intent by "circular" argument that attorney and inventors failed to inform each other of material information.)

Apart from such testimony, Eisai's submissions disclaiming deceptive intent amount to repetitions of its arguments disclaiming materiality, in effect urging that bad faith may not be inferred from such immaterial nondisclosures. (See P. Mem. 35-36, 43-44; see P. Reply Mem. 10-17, 23-27.) To the extent plaintiffs rely on their professed belief that their March 1989 comment to Fan about asymmetrical substitution was not an argument for patentability, their interpretation of Fan's "not understood" reply as a dismissal of the comment, the fact that Fan never openly expressed an understanding that Junggren did *not* show asymmetry, and the fact that Fan had known from the beginning that Junggren was prior art to rabeprazole (see Killworth Decl. ¶¶ 113, 114), these arguments simply raise questions of credibility. As demonstrated above, however, genuine issues of fact exist as to the degree of materiality of the nondisclosures, and a reasonable factfinder could reject Eisai's claims of good faith based on a finding that the '013 rejections were highly and clearly material.

Finally, Eisai stresses the lack of "smoking gun" evidence of deceptive intent, which the law of inequitable conduct does not require. Regarding the '013 patent examiner's citations of

Byk Gulden, for instance, plaintiffs insist that "[t]here is absolutely no evidence that the Byk Gulden . . . patent was considered by Eisai in any context at any time to be relevant to the claims of the '552 patent" or that Eisai's attorneys or inventors "ever saw the Byk Gulden . . . patent." (P. Mem. 35-36.) But decrying defendants' failure to show direct evidence of culpable knowledge does not negate their showing of notice and materiality of the nondisclosures, from which deceptive intent could be inferred.[39] See, e.g., GFI, Inc., 265 F.3d at 1268. There is no dispute that Eisai received the ethyl homolog rejections. Those rejections, as with those in the '552 patent prosecution, were at most several pages long and provided succinct conclusions explicitly citing the prior art, including Byk Gulden. Since Eisai pursued the '013 patent application through several rejections, a reasonable factfinder could easily infer that someone on behalf of Eisai must have reviewed and considered the content of those rejections. In that event, and should that content be found highly material, a reasonable factfinder could infer that Eisai deliberately withheld information about the rejections from the '552 examiner in order to keep her from learning the bases of those rejections.

---

[39] The only direct evidence defendants submit to show plaintiffs' culpable knowledge is a document in which the methoxypropoxy disclosure of Byk Gulden is highlighted; defendants claim the disclosure was circled by Eisai's internal head of patenting, Taniguchi, in an indication of his appreciation of its significance. (Teva Mem. 35, citing Teva Ex. 54.) Eisai counters that the document was marked up in connection with this litigation and thus is not evidence of Taniguchi's awareness at the relevant time. (P. Reply Mem. 14.) This factual dispute cannot be resolved on summary judgment.

Another piece of purported evidence of bad faith offered by Teva suffers from gross inaccuracy. Teva quotes Eisai's Crawford as admitting that rabeprazole and the ethyl homolog were "structurally patentably indistinct," suggesting that he knew the '013 patent application was material for the fact of its co-pendency and for the fact and substance of its rejections. (Teva Mem. 33.) In fact, when asked by Teva's attorney whether he held this view, Crawford answered, "I don't have any background information to determine if one is patentably distinct from the other . . . . I can't answer that question." (Teva Ex. 60, Crawford Tr. 230:1-231:6.)

Defendants have argued that, "[b]ecause Eisai could not have made its argument for patentability had the Byk Gulden reference or the rejections based on the combination of Junggren and Byk Gulden been disclosed, intent to deceive is apparent." (Teva Mem. 34, citing GFI Inc., 265 F.3d at 1275 (deceptive intent may be inferred where applicant withholds a reference and "makes an argument for patentability that could not have been made had the art been disclosed").) While the degree to which the Byk Gulden and Junggren references may have precluded arguments for rabeprazole's patentability remains to be determined at trial, for now defendants have succeeded in showing a sufficient basis upon which a reasonable factfinder could decide, by clear and convincing evidence, that the undisclosed information from the ethyl homolog rejections was known and significantly material, and that applicant's intent to deceive should thus be inferred.

II. Misleading Representations in the "Fujisaki Declaration"

Defendants also charge that Eisai engaged in inequitable conduct by submitting a misleading response, the Fujisaki Declaration, in its final bid to secure the '552 patent.[40] Defendants essentially claim that Eisai acted with deceptive intent by asserting structural and performance arguments in rabeprazole's favor, while omitting contradictory information about the ethyl homolog and Byk Gulden. (See Teva Mem. 36-42; Reddy Mem. 38-41.)

Defendants argue that certain test data relating to the ethyl homolog would have undermined Eisai's claim, based on the Fujisaki Declaration, that "the compound of the

[40] There is no dispute that the Fujisaki Declaration and accompanying commentary were highly material under the reasonable examiner standard. The declaration was made pursuant to a regulation that enabled applicants to address and attempt to overcome PTO rejections, and there is no indiction that Eisai intended these submissions to serve any other purpose.

invention having a methoxy-propoxy at the 4' position of the pyridine ring . . . exhibits surprisingly unexpected [acid-]inhibitory effects . . . in comparison with closely related compounds of the type referred to by the examiner." According to examiner Fan's prior statements, that "type" would include Junggren Example 27, which, like the ethyl homolog, bears a methoxyethoxy substituent at the 4-position of the pyridine ring; defendants thus urge that Eisai must have known that data regarding the ethyl homolog would be similarly material to the examiner. (Teva Mem. 37-38.) Defendants read Fan's statement that "only methoxyethoxy cpd need [*sic*] to be compared" as meaning that Eisai should submit comparisons of methoxyethoxy-substituted PPI compounds generally, not just of one.[41] Since the ethyl homolog is just such a compound, and since Eisai obviously knew about it, defendants contend, Eisai intentionally deceived by failing to compare it. They submit Eisai-created data of the type portrayed in the Fujisaki Declaration for the ethyl homolog, along with evidence that the data are "comparable" to those for rabeprazole – thereby urging that rabeprazole was not distinctively superior. (Teva R. 56.1 Stmt. ¶ 149, citing Teva Ex. 82, internal Eisai test data, and Forte Decl. 1 ¶¶ 51, 54.) Defendants contend that Eisai knew the ethyl homolog data would undercut its case for rabeprazole and, with deceptive intent, omitted them from its final submission in the '552 patent prosecution. (Teva Mem. 40-41; Reddy Mem. 40.)

These contentions also raise issues of fact. Eisai first argues that it had no duty to disclose any data relating to the ethyl homolog in the Fujisaki Declaration, as it is "undisputed" that the compound was not prior art, and, "if a compound were not a prior art compound, then

---

[41] See note 13 supra and accompanying text, for facts of Fan's writing and different interpretations.

patent practitioners understood there would be no need to submit data for that compound." (P. Mem. 26-27; see also P. Reply Mem. 4-6.) This argument fails to negate a genuine issue of fact as to its conduct, as it has not yet been resolved whether the ethyl homolog was disclosed in the prior art. (See Teva R. 56.1 Stmt. ¶ 153, citing Smith Decl. ¶¶ 179-80.)

Eisai next argues that the Fujisaki Declaration fully addressed the comparison examiner Fan sought. Plaintiffs read Fan's "methoxyethoxy cpd" statement as demanding one comparison only, to Junggren Example 27. (P. Mem. 27.) But as with other disputes regarding the meaning to be accorded to Fan's statements, Eisai has offered no evidence sufficient to preclude defendants' equally plausible reading of the statement. Especially since Fan's writing memorialized a verbal exchange between her and Crawford, the determination of what Eisai should have understood Fan to mean, and what data should have been disclosed in its response, must await a trial involving cross-examination and credibility findings.[42]

A final charge relating to the Fujisaki Declaration, however, cannot survive the summary judgment stage. Reddy contends that Eisai engaged in misconduct by submitting in vitro test data with the "implicit representation" that such data and the method used to produce them provided a "reliable and meaningful assessment of [a] compound's ability to inhibit the secretion of gastric acid," that is, of in vivo activity. (Reddy Mem. 39; see Reddy R. 56.1 Stmt. ¶ 260.) The allegation is exceedingly narrow: Reddy does not claim, for instance, that the submitted data themselves were faulty or otherwise inaccurate representations of the in vitro results they

[42] Defendants also argue that Eisai should have disclosed the Byk Gulden reference in the Fujisaki Declaration and compared its asymmetrically-substituted methoxyethoxy compounds. (Teva Mem. 38-39; Reddy Mem. 41.) These arguments are for the most part repeat the arguments regarding the materiality of Byk Gulden, already discussed.

purported to be. Nor does Reddy counter Eisai's evidence that the in vitro test is an accepted measure of potency. (See P. Reply Mem. 9 for citations to record relevant to the test.) Nor does Reddy demonstrate a material misrepresentation because a reasonable examiner of rabeprazole would have taken the in vitro comparison to account for all the effects of a claimed compound; the Fujisaki Declaration called it "*an* assessment" of the compound's pharmacological effect – not the best, or the only. The comparative data submitted amounted to a single page and could hardly be taken by a reasonable person, much less a reasonable examiner, to be exhaustive of all Eisai's internal research.

Thus, Reddy does not charge that Eisai misrepresented either the nature of its studies of the resulting data, or that it withheld material contrary data, but rather alleges an "implicit misrepresentation" that in vitro data reliably predicted in vivo results. No such representation can be gleaned from Eisai's actual submission. While Reddy may have raised valid doubts as to the thoroughness of Eisai's presentation, no reasonable factfinder could, by clear and convincing evidence, decide on this record that Eisai so egregiously (though only "implicit[ly]") misrepresented the data it disclosed that it engaged in inequitable conduct.

III. Misleading Presentation of Omeprazole-Comparison Data

Defendants next argue that Eisai committed inequitable conduct by materially misrepresenting data to show rabeprazole to be more potent than omeprazole, the active ingredient in the then most prominent drug of the class, Prilosec, and the clinical "gold standard." (See Teva R. 56.1 Stmt. in Opp. to P. Mot. for Summ. J. of Patent Validity ¶ 63.) In its patent application, Eisai had included three sets of pharmacological data comparing omeprazole to rabeprazole. (Ds. Joint R. 56.1 Stmt. ¶ 37.) The first, from an in vitro test, was

said by Eisai to indicate rabeprazole's superior potency, because less of it than of omeprazole was required to inhibit proton pump activity. The second, from an experiment in dogs (the "histamine dog test"), was also reported by Eisai to demonstrate rabeprazole's superior potency. The third set of data also arose from a test in dogs (the "pentagastrin dog test") and was reported by Eisai as showing a faster post-dosage recovery of acid secretion for rabeprazole than for omeprazole, an effect that Eisai represented to be beneficial. (P. R. 56.1 Stmt. ¶¶ 19, 21, 23-27, 36-39.) Eisai repeatedly argued favorable performance comparisons to omeprazole during its prosecution of the rabeprazole claims.

Defendants charge deliberate, material omissions in the presentation of data from the histamine dog test and from the pentagastrin dog test. They offer documentary and testimonial evidence that the specific comparison selected from the histamine dog test data lacked statistical significance and that relevant Eisai inventors knew as much. (See Teva Mem. 43, 45 and related citations to record in Teva R. 56.1 Stmt. ¶¶ 167, 174-179; Reddy Mem. 41-42, 45-46 and related citations to record in Reddy R. 56.1 Stmt. ¶¶ 274-75, 288, 291-92, 296-312.) Defendants allege that Eisai received notice of this problem in the form of rejections of a related manuscript it had submitted to a science journal during the '552 patent prosecution. (See Teva. Mem. 45-46; Reddy Mem. 45.) They also point out that Eisai disclosed the statistical analysis in its application to the FDA and argue that such disclosure suggests Eisai was aware of the significance of the information and therefore intentionally and deceptively withheld it from the PTO. (See Teva Mem. 46; Reddy Mem. 43, 46.)

Regarding the pentagastrin dog test, defendants charge that Eisai deliberately dissembled by submitting only data relating to post-dosage recovery while withholding other data showing

nearly equivalent potency as between omeprazole and rabeprazole during certain time spans of use. They once again urge that Eisai's knowledge and deliberate withholding of this undisclosed data may be inferred from their later submission to the FDA. (See Teva Mem. 44-46 and related citations to record in Teva R. 56.1 Stmt. ¶¶ 169-70, 180-88; Reddy Mem. 42-43 and related citations to record in Reddy R. 56.1 Stmt. ¶¶276-77, 288-91, 317.)

Finally, defendants allege that Eisai culpably withheld all data from yet another test (the "pylorus-ligated rat test"), that did not merely belie rabeprazole's superiority to omeprazole, but, further, showed omeprazole to be the more potent compound. They offer as evidence of culpable knowledge documents produced from Eisai and the fact that Eisai disclosed the data in its submission to the FDA. (See Teva Mem. 44-46 and related citations to record in Teva R. 56.1 Stmt. ¶¶ 171, 173, 187-93; Reddy Mem. 42-43 and related citations to record in Reddy R. 56.1 Stmt. ¶¶ 278, 288-90, 317.)

For defendants to prevail on these charges, they must show at the least that the partially disclosed or undisclosed data were material to the rabeprazole prosecution. They argue that Eisai rendered the information material by "repeatedly presenting rabeprazole's alleged superior potency over omeprazole as an argument for patentability." (Teva Mem. 42-43.) Eisai does not dispute that it made numerous submissions professing rabeprazole's superiority to omeprazole, but it counters that "*no* comparisons between omeprazole and rabeprazole would have been important to the examiner's decision . . . because . . . the *examiner expressly made clear that she was not interested in omeprazole*." (P. Mem. 19, emphases added.) Once again, the parties dispute the meaning of Fan's comments rejecting Eisai's attempt indirectly to compare

rabeprazole to Junggren Example 27 via comparisons of omeprazole to those two compounds.[43] This disagreement over the underlying facts necessary to evaluate the status of substantive facts, alone, suggests the need to reserve judgment on these charges for after trial. In any event, whatever Fan meant, the duty of disclosure is neither legally nor logically limited to information affirmatively indicated by the examiner to be important, as the duty would then add little to the patenting process. While Fan's views as to the importance of omeprazole are certainly relevant, they are not dispositive of what a reasonable examiner would have found relevant. Given Eisai's own insistence during the prosecution process that comparisons to omeprazole were significant, it cannot now escape a claim that its comparisons were distorted by contending that no reasonable factfinder could regard the comparisons as having any significance.

Moreover, defendants remind that the inequitable conduct inquiry does not require information to reach a "but for" level of importance to be considered material. See, e.g., Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1421 (Fed. Cir. 1989) (rejecting a "but for" standard of materiality). In other words, they argue, even if the data in issue would not have changed the ultimate patenting decision, they may be deemed material given Eisai's representations in the prosecution. (Teva Mem. 42-43.) Indeed, it need not be proved that an examiner necessarily relied on the challenged submissions to show materiality, especially where, as here, the applicant repeatedly made patentability arguments that may be found inconsistent with actual data. See Purdue Pharma L.P., 438 F.3d at 1132. That Eisai eventually shifted to arguing rabeprazole's superiority over another compound does not necessarily erase the effect of

[43] See note 13 supra and accompanying text, for Fan's July 14, 1989, rejection and the parties' disparate readings thereof.

its earlier arguments regarding omeprazole; all such arguments went to urging rabeprazole's distinctive performance. What is more, there is no way to know exactly which submissions persuaded Fan to issue the rabeprazole patent. Construing the existing record in the light most favorable to defendants, it is clear that a reasonable factfinder could find that a reasonable examiner of rabeprazole would have wanted to know about contradictory or unpersuasive data from comparisons with omeprazole.

Yet, Eisai insists, even if omeprazole-related information were deemed material, the data withheld or partially disclosed were not in fact contradictory to rabeprazole's case. (P. Mem. 22.) Eisai's expert submissions and interpretations of defendants' expert evidence, however, do not manage to negate all genuine issues of material fact defendants have raised on the matter. (See P. Mem. 22-26, especially for representations about defendants' expert testimony, which in places conflict with reports actually submitted by those experts.) The question of the materiality on the reasonable examiner standard of the various withheld or selected data largely boils down to a battle of experts that will require cross-examination and findings of credibility to resolve.

Nevertheless, it must be noted that defendants face an unusually high hurdle in proving inequitable conduct on this particular set of allegations. In patent cases, courts have found less suspect applicants' choices in presenting scientific data than they have, for instance, applicants' concealment of key prior art references. See, e.g., Purdue Pharma L.P., 438 F.3d 1123 (in part vacating finding of inequitable conduct, because trial court erroneously found patentee's implication of a nonexistent scientific finding to be so highly material that deceptive intent should be inferred). Further, affirmative misrepresentations may be considered more material, and thus more suggestive of deceptive intent, than are misleading omissions. Hoffman-La

Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1367 (Fed. Cir. 2003). Certainly, extremely misleading presentation of experimental data can constitute equitable conduct. For example, the Federal Circuit reversed a trial court's finding of no inequitable conduct where a patentee had literally *altered* experimental data, presented results from different readings as if they were from the same, and entirely omitted one body of data, in affidavits explicitly intended to overcome PTO rejections and relied upon to that end. Rohm and Haas Co. v. Crystal Chemical Co., 722 F.2d 1556, 1562, 1570-71 (Fed. Cir. 1983). But the inherently selective nature of presentations that cannot possibly disclose *all* data from experimental work suggests caution in permitting competitors, after the fact, to defeat patent enforcement by highlighting stray bits of unfavorable experimental data that did not find their way into an otherwise accurate presentation.

Moreover, the Federal Circuit has specifically counseled against imputing deceptive intent merely from differences between the data submitted by an applicant to the PTO and to the FDA. Purdue Pharma L.P., 438 F.3d at 1134 (Fed. Cir. 2006) ("the quantum of proof necessary for FDA approval is significantly higher than that required by the PTO"); see also Pfizer Inc. v. Ranbaxy Laboratories Ltd.,405 F. Supp.2d 495, 523-24 (D. Del. 2005), rev'd in part on other grounds, 457 F.3d 1284 (Fed. Cir. 2006) (stating that "a determination of materiality before the PTO is not governed by that which is required for submission to the FDA," and distinguishing Federal Circuit precedent finding deceptive intent based on a patentee's submission of *prior art* references to the FDA but not to the PTO); cf. Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., 394 F.3d 1348, 1350 (Fed. Cir. 2005) (affirming finding of deceptive intent based on patentee's disclosure of *prior art* to the FDA but not to the PTO). As Eisai correctly argues, "A

patent is not a scientific journal or an FDA submission."[44] (P. Mem. 20.)

Thus, while it appears unlikely that defendants can prevail on these charges, it is impossible to say on this record that the particular allegations about Eisai's selective presentations of data could not support findings of materiality and deceptive intent sufficient to sustain a judgment of inequitable conduct.

IV. Nondisclosure of Lansoprazole Application

Finally, Teva alone alleges that Eisai committed inequitable conduct by failing to inform examiner Fan of a prior-art application regarding the compound lansoprazole, another proton pump inhibitor that is the active ingredient of yet another competing drug, Prevacid. (Teva Mem. 47-50.) Summary judgment for Eisai must be granted as to this allegation, because Teva has presented neither direct evidence of deceptive intent nor evidence of materiality such that intent could properly be inferred.[45]

For purposes of this motion, the Court assumes that Teva is correct that a reasonable factfinder could make the following factual findings regarding lansoprazole. Lansoprazole, claimed in a patent owned by Takeda Pharmaceuticals, was the second commercially available proton-pump inhibitor after omeprazole. (Teva Mem. 5.) Its structure resembles that of

---

[44] Eisai's repeated denials that its inventors "believed" the disputed data to be relevant or contradictory to the rabeprazole prosecution are, for reasons discussed throughout this opinion, inapposite to the materiality inquiry. (See P. Mem. 25-26.) The materiality standard necessarily does not depend on an applicant's subjective views. To the extent that Eisai means these professions to negate evidence of deceptive intent, it is once again noted that testimony of ignorance or innocence, while clearly relevant, simply presents issues of credibility for the factfinder where material data known to the applicant have been withheld.

[45] In a separate Opinion and Order of this date, the Court rejects Teva's related argument that lansoprazole enables a prior-art combination that would have rendered rabeprazole unpatentably obvious. (Teva Mem. 47-48).

rabeprazole, with a pyridine ring that differs only by a fluorinated alkoxy substituent at the 4-position. (Id.) The lansoprazole patent application included data from a single test on rats showing the compound to be over 20 times more effective against ulcers than omeprazole. (Id. at 6.) Lansoprazole was cited to the European examiners of rabeprazole.[46] (Id. at 48.) An Eisai inventor heard from another attendee of a pharmacology conference, who "apparently" had attended a presentation by lansoprazole's own inventor, that lansoprazole was said to be "as good or better than omeprazole at inhibiting acid secretion." (Teva R. 56.1 Stmt. ¶¶ 200, 201.) Eisai inventors otherwise had knowledge of and substantively evaluated lansoprazole before claiming rabeprazole. (Teva Mem. at 6, 49.) One Eisai insider commented at an internal meeting during the rabeprazole prosecution that the "similarity" of the two compounds "bothers me." (Teva R. 56.1 Stmt. ¶ 208.) Eisai did not disclose the lansoprazole application to rabeprazole's examiner. (Teva Mem. 47.)

On this showing, Teva argues, "[i]ntent to deceive should be inferred." (Teva. Mem. 49.) Yet while sufficient to prove some degree of materiality, this record is inadequate to persuade a reasonable factfinder by the clear-and-convincing standard that Eisai withheld information of lansoprazole with intent to deceive the '552 patent examiner. The available evidence cannot sustain "a confident judgment that deceit has occurred" on this issue. Akron Polymer, 148 F. 3d

---

[46] Teva does not dispute Eisai's elaboration here: Eisai points out that a *third-party competitor* – not Eisai or the patent examiners – cited lansoprazole in the European patent process. The Court agrees with Eisai that Teva's implied argument based on Molins PLC v. Textron, Inc., 48 F.3d 1172 (Fed. Cir. 1995), that Eisai should therefore be held accountable for not disclosing lansoprazole to the U.S. examiner, is thus inapposite. (P. Reply Mem. 30: "In Molins, the *patent applicant* cited the undisclosed reference and said it was the most relevant, and the European examiners considered it material. Here . . . a third-party[] tried to cite lansoprazole to the European examiner"; emphasis added.) Eisai's European application to rabeprazole was not thereafter denied. (P. Mem. 45-46; P. Reply Mem. 30-31.)

at 1384.

There is no dispute that a considerable class of similarly structured compounds existed, and that Eisai evaluated a number of them before filing the rabeprazole application. (See Teva R. 56.1 Stmt. ¶ 203.) The secondhand report of lansoprazole's being "as good as or better than" omeprazole, evidently originating with the creator of lansoprazole itself, would, sensibly, require weighing with much restraint. That an Eisai insider – who Teva does not suggest was an expert or even involved with the rabeprazole prosecution – was bothered by the similarity of the two compounds would hardly suffice to prove Eisai knew or should have known that lansoprazole could render rabeprazole unpatentable.

Of all Teva's submissions, the data showing lansoprazole to be over 20 times more effective than omeprazole in one test would seem to promise the most powerful showing of materiality. But that is only because defendants have shown that certain *omeprazole*-related information could be so significant, by noting evidence that Eisai had made representations to the PTO comparing rabeprazole to omeprazole. To find lansoprazole data markedly material by this indirect relationship, and to the extent that its nondisclosure could engender an inference of deceptive intent, is not reasonably possible. Lansoprazole is certainly in a broad sense relevant to the rabeprazole application, but what Teva fails to provide here – and what defendants have succeeded in providing elsewhere – is a probative showing that Eisai knew or should have known the withheld information was important to the rabeprazole prosecution before the PTO and that it could thus be charged with intent to deceive. Defendants have successfully shown, for instance, that Eisai arguably knew the importance of other information because it received PTO-rejections in a substantially similar prosecution, or because it affirmatively made closely

related arguments to the PTO about rabeprazole's properties. These showings suggest significant materiality of the nondisclosed information to the rabeprazole prosecution and, thus, the possibility of inferring deceptive intent. Teva makes no such showing with regard to lansoprazole; the report of improved anti-ulcer performance in rats in a single test does not suggest that Eisai must have appreciated, at the time of the prosecution of the rabeprazole patent application, that lansoprazole would be of importance to a reasonable patent examiner. The case law precludes the finding of inequitable conduct where there is no plausible basis for inferring deceptive intent: "Intent to deceive can not be inferred solely from the fact that [relevant] information was not disclosed; there must be a factual basis for a finding of deceptive intent." Atofina v. Great Lakes Chemical Corporation, 441 F.3d 991, 1002 (Fed. Cir. 2006), quoting Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996).

CONCLUSION

For the foregoing reasons, plaintiffs' motion for summary judgment of no inequitable conduct is denied in part and granted in part.

SO ORDERED.

Dated: New York, New York
October 5, 2006

GERARD E. LYNCH
United States District Judge